

Exhibit 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CONFORMIS, INC.,

Plaintiff,

v.

DEPUY SYNTHES, INC., DEPUY SYNTHES
PRODUCTS, INC., and DEPUY SYNTHES
SALES, INC.

Defendants.

C.A. No. 21-640-RGA

JURY TRIAL DEMANDED

DEFENDANTS' PRELIMINARY INVALIDITY CONTENTIONS

Pursuant to the Scheduling Order, Defendants DePuy Synthes, Inc., DePuy Synthes Sales, Inc., and DePuy Synthes Products, Inc. (“Defendants”) hereby serve their preliminary Invalidity Contentions on Plaintiff Conformis, Inc. (“Conformis” or “Plaintiff”).

I. INTRODUCTION

Defendants are relying on Conformis’s disclosures as set forth in their infringement contentions, which are deficient, and Defendants’ best understanding of Conformis’s implicit claim constructions, in selecting and characterizing prior art herein. Any assertion that a particular limitation is disclosed or rendered obvious by a prior art reference or references is not an admission that such constructions are supportable or proper.

The accompanying disclosures, including the claim charts, contain specific examples of prior art references, patents, knowledge, inventions, uses, sales, methods, and/or systems which disclosed, either expressly or inherently, each limitation of certain claims and/or examples of prior art references and systems in view of which a person of ordinary skill in the art would have considered each limitation and the claimed combination of such limitations obvious. Defendants have endeavored to identify relevant portions and/or features of the identified prior art. The identified prior art, however, may contain additional descriptions of or alternative support for the claim limitations. Defendants may rely on un-cited portions or features of the identified prior art, other documents, and expert testimony to provide context or to aid in understanding the identified prior art. Where Defendants cite a particular figure in a reference, the citation should be understood to encompass the caption and description of the figure and any text relating to the figure. Similarly, where Defendants cite particular text referring to a figure, the citation should be understood to include the figure and caption as well.

Defendants take no position on any matter of claim construction in these contentions, since the Court has not yet construed the claims. Any statement herein describing or tending to describe any claim element is provided solely for the purpose of understanding the relevant prior art in view of the current stage of the case, including the constructions implicit in Plaintiff's infringement contentions. Defendants expressly reserve the right to propose any claim construction they consider appropriate and/or to contest any claim construction they consider inappropriate. Furthermore, this document may reflect alternative positions as to claim construction and scope. Accordingly, nothing in this document should be construed as an admission as to any particular claim construction position or that any claim of the Asserted Patents is valid, enforceable, or infringed. Similarly, the identification of prior art that anticipates and/or renders obvious a particular claim element in these contentions is not an admission that the claim element satisfies other requirements of patentability, such as those codified in 35 U.S.C. § 112. Where Defendants assert that a claim is invalid under 35 U.S.C. § 112, they nonetheless provide prior art that anticipates or renders obvious the claim based on Plaintiff's apparent contrary position.

Defendants reserve the right to revise their contentions concerning the invalidity of the asserted claims, which may change depending upon (for example) the Court's construction of the asserted claims, additional information obtained during the discovery period, any findings as to the priority date of the asserted claims, and/or any positions that Plaintiff, Defendants, or any witness may take concerning claim construction, infringement, and/or invalidity issues.

Defendants further intend to rely on inventor admissions concerning the scope of the asserted claims, and prior art relevant to the asserted claims, for example, as found in: the Asserted Patents; the patent prosecution history for the Asserted Patents (including documents submitted therein) and related patents and/or patent applications; any deposition testimony of any inventor

of the Asserted Patents; and any papers filed or any evidence produced or submitted by Conformis or its affiliates in connection with this litigation and other legal proceedings, related to the Asserted Patents or related patents.

Prior art not included in these contentions, whether known or not known to Defendants, may become relevant. For example, Defendants are currently unaware of the extent, if any, to which Conformis will contend that limitations of the Asserted Claims are not disclosed in the prior art identified. Defendants reserve the right to identify additional references that would disclose or render obvious the allegedly missing limitation(s), if Conformis identifies any. Further, discovery is ongoing. Thus, Defendants reserve the right to revise, amend, and/or supplement the information provided herein, including identifying, charting, and relying on additional references, should Defendants' further search and analysis yield additional information or references. Prior art references included in these preliminary Invalidity Contentions may be related (e.g., as a divisional, continuation, continuation-in-part, parent, child, or other relation or claim of priority) to earlier or later filed patents, publications, or systems, may have counterparts or related references filed or published in other jurisdictions, or may incorporate (or be incorporated by) other patents, publications and systems by reference. The listed references are intended to be representative of these other patents, publications, and systems.

Additionally, Defendants reserve the right to present additional items of prior art to the extent that such discovery or investigation yields information forming the basis for such contentions of invalidity. For example, third parties may have knowledge, documentation, and/or corroborating evidence concerning some of the prior art identified in the accompanying claim charts and Exhibit A and/or additional prior art, including third party systems, sales, offers for sales, knowledge, or use mentioned in or otherwise relevant to the references discussed herein.

II. IDENTIFICATION OF PRIOR ART

The prior art references identified in the accompanying claim charts and Exhibit A, alone and/or in combination with any other prior art references disclosed herein (or disclosed in the prosecution histories of the Asserted Patents) anticipate and/or render obvious each of the Asserted Claims at least for the reasons provided in the enclosed claim charts and Exhibit A. The references identified in the accompanying claim charts and Exhibit A are prior art under at least 35 U.S.C. §§ 102(a), (b), (e), (g), and/or 35 U.S.C. § 103. Each of these references may also reflect prior knowledge, prior public uses, and prior invention by others. Additionally, Defendants reserve the right to rely on uncited portions of the identified prior art, other prior art, references that show the state of the art irrespective of whether such references themselves qualify as prior art to the Asserted Patents, and/or expert testimony to provide context to or aid in understanding the cited portions of the identified prior art.

Defendants not only rely on the prior art documents disclosed herein, but also on any commercial embodiments and accompanying literature of the various assignees that correspond to the respective disclosures found within the prior art disclosed herein. The assignees' various and respective commercial embodiments and/or corresponding literature anticipate and/or render obvious the claims of the Asserted Patents for at least the reasons disclosed in these preliminary Invalidity Contentions and claim charts, as well as for other independent reasons found within the commercial embodiments and corresponding literature. Defendants' investigation and understanding of the prior art sales, offers for sale, use, and knowledge is not complete, and Defendants reserve the right to use both the evidence cited herein, as well as other specific information developed through fact discovery, to establish that the asserted claims are invalid under 35 U.S.C. §§ 102(a), (b), and (g).

Specific illustrative examples of prior art products or systems sold, offered for sale, used and/or known, based on Defendants' preliminary investigation, include the PFC Sigma RP Knee products by Johnson & Johnson and other products identified on the face of the patent and the prior art references, and the OtisKnee system.

III. INVALIDITY CONTENTIONS

A. General State of the Art at the Time of the Alleged Inventions

Additional prior art may provide background and context pertinent to the teachings, and interpretation of, the prior art referenced by the claim charts, including, for example:

- the prior art references and systems identified in the accompanying claim charts and Exhibit A, and as described in the attached claim charts and Exhibit A;
- prior art references and systems discussed in the Asserted Patents and their prosecution histories; or
- the "References Cited" on the face of the Asserted Patents.

Defendants intend to rely on such prior art to demonstrate the general state of the art at the time of the alleged inventions and what one of ordinary skill in the art would have understood at a time prior to the date of alleged invention of the Asserted Claims of the Asserted Patents. This prior art is exemplary only and is not in any way intended to limit the scope of what one of ordinary skill in the art would have understood at the times of the alleged inventions. Defendants reserve the right to rely upon additional prior art, information, and/or knowledge to demonstrate what one of ordinary skill would have understood at the times prior to the date of the alleged invention of the Asserted Patents.

B. Prior Art Claim Charts

The claim charts submitted herewith identify specifically where each limitation of each

claim is found in each charted prior art reference, either expressly or inherently as understood by a person having ordinary skill in the art, at least under the constructions implicit in Plaintiff's infringement contentions. Each prior art reference that has been charted anticipates the claims of the Asserted Patents. Additionally, herein and further in the attached claim charts and Exhibit A, Defendants identify prior art references that either alone or in combination with other prior art, and/or when combined with the knowledge of one of ordinary skill in the art, render the Asserted Claims invalid as obvious under 35 U.S.C. § 103. For avoidance of doubt, the illustrative obviousness combination provided in certain charts are by way of example only, and not by way of limitation. For example, for many elements, additional references and/or additional detail regarding motivations to modify and combine are provided in Exhibit A. These additional reference and motivations are equally applicable.

In the attached claim charts, Defendants have referred to representative portions of the cited prior art. The absence of any specific or express reference to any claim term or claim element in these charts should not be construed as an admission that any corresponding limitation is lacking either expressly or inherently in the prior art reference. There may be additional support or other grounds for Defendants' Preliminary Invalidity Contentions that such prior art satisfies a particular claim element, and Defendants reserve the right to rely on such information. For example, persons of ordinary skill in the art at the time of the filing of the Asserted Patents knew to read relevant surrounding text, and to consider documents in the context of other publications and literature and the general knowledge in the field. Defendants may rely on all such information, including uncited portions of the prior art references listed herein, and on other publications and expert testimony, to provide context and as aids to understanding and interpreting the listed references, or to establish that a person of ordinary skill in the art would have been motivated to modify or combine any of

the cited references so as to render the claims obvious. Additionally, citations to a particular figure in a prior art reference encompass all text relating to the figure, and citations to text encompass all figures relating to or referred to by that text. Defendants expressly reserve the right to supplement these Preliminary Invalidity Contentions to include further information obtained in discovery.

C. Obviousness and Motivations for Combining Identified Prior Art

Based on Defendants' present understanding of the claims of the Asserted Patents, each of the prior art references identified in the accompanying claim charts and Exhibit A and charted in the attached Exhibits standing alone also renders the claims obvious in view of the knowledge of a person of ordinary skill in the art as of the time of the alleged invention. It would have been obvious to one of ordinary skill in the art, applying their own knowledge, to modify any of the prior art references to arrive at that which is claimed in the Asserted Patents, including for the reasons described in the charts and in Exhibit A hereto.

The Asserted Claims would also have been rendered obvious based on a combination of two or more of the prior art references identified in the accompanying claim charts and Exhibit A and charted in the attached Exhibits, including for the reasons described in the charts and in Exhibit A hereto. One of ordinary skill in the art at the time of the purported invention would have been motivated to combine each of the identified references. In general, motivation to combine any of the identified references with others exists within the references themselves, as well as within the knowledge of those of ordinary skill in the art. For example, a person of ordinary skill in the art at the time of the purported invention would have been motivated to modify the prior art or combine prior art references as a result of (i) his or her education and experience, (ii) the state of the prior art as a whole, (iii) the nature of the problem to be solved, (iv) common knowledge in the art, (v) common sense, (vi) design incentives, (vii) market forces, and/or (viii) a desire to tailor a

solution using all of the skills, knowledge and creativity at his or her disposal. As further examples, motivations to combine each of the prior art references identified in the accompanying claim charts and Exhibit A include one or more of the following:

- The references are within the same field, e.g., joint surgery, imaging, and surgical guides, are directed at solving similar problems, disclose solutions with similar advantages, and existed in the same time period as each other;
- The references are in a relatively established art such that combining known prior art elements such as those claimed by the Asserted Patents would yield predictable results;
- The knowledge or common sense of a person of ordinary skill in the art, who would be involved for example in the use of computers and medical imaging for surgery and in designing surgical instrumentation;
- The prior art references themselves, many of which discuss, incorporate by reference, or cite to other prior art references;
- The cited references explicitly or implicitly reference other prior art references, share common authors or inventors or assignees, were published in the same journals, presented at the same conferences, or were developed in common companies, organizations or industries which would motivate one of skill in the art to combine them; and
- The fact that many of the references include teachings, suggestions, or motivations to modify the disclosed subject matter, making it obvious to lead one skilled in the art to try to modify or combine their teachings, or to choose from the multiple identified, predictable potential solutions to this recognized need and pursue the known potential solutions with reasonable expectation of success.

These and other motivations to combine references would have been within the knowledge generally available to one of ordinary skill in the art and/or located in the references themselves.

It would have been obvious to one of ordinary skill in the art to try combining the identified prior art references because there were only a finite number of predictable solutions. Further, known work in one field of endeavor would prompt variations based on predictable design incentives and/or market forces either in the same field or a different one, and the combinations represent the known potential options with a reasonable expectation of success. The combinations and modifications of the prior art that arise from the fact that references are from the same or related fields, and based on ordinary innovation in the field, the ordinary skill in the field, the common sense of those skilled in this art, the express and implicit teachings, suggestions and/or motivations in these references, the common sense to combine elements to arrive at the claimed inventions, and that it would have been obvious to try the various combinations of elements, yielding a particular result, with a reasonable expectation of success and with predictability.

Additionally, to the extent that the Plaintiff alleges that certain elements are missing from any of the charted references, those elements are known in the art or would be inherent in the relevant context. One of skill in the art would have understood that a limited number of different approaches could be taken depending on the design needs and would have combined those approaches to meet the various design needs.

Any reference or combination of references that anticipates or makes obvious an independent claim also makes obvious any claim dependent on that independent claim because every element of each dependent claim was known by a person of ordinary skill at the time of the alleged invention, and it would have been obvious to combine those known elements with the independent claim at least as a matter of common sense and routine innovation. Accordingly,

Defendants contend that each claim would have been obvious not only by the combinations explicitly defined in these contentions, but also by any combination of references that renders obvious that claim.

To the extent Plaintiff contends that any reference contains multiple distinct embodiments, it would be obvious to combine elements of the distinct embodiments. A person would be motivated to make such a combination because the elements are found in the same reference and the reference as a whole is directed to the same topic.

D. Secondary Considerations

To date, Plaintiff has not presented any evidence of secondary considerations of non-obviousness, and Defendants are not aware of any such evidence. To the contrary, the alleged inventions of the patents were already known in the art, and there is no apparent nexus between any allegedly inventive aspects of the patents and any commercial success, recognition, or praise of any product. Similarly, there is no evidence of the patents addressing any long-felt needs not already addressed by other methods known in the art, or any evidence of failure of others, copying, skepticism, or unexpected results. Defendants reserve the right to respond in the event that Plaintiff makes any allegations regarding secondary considerations.

E. Invalidity Under 35 U.S.C. § 112

1. Indefiniteness

At least the following claim terms, in the context in which they are used in the claims, are invalid for indefiniteness, at least based on the current positions that Conformis appears to be taking regarding claim scope, the understanding of a person of skill in the art, and the disclosures of the specification and intrinsic record. Additionally, Defendants reserve the right to assert other

indefiniteness arguments that become apparent during the claim construction process or during fact or expert discovery.

- The “Rotation Angle” Limitations (Exhibit A, Section I)
- “Anatomical Axis” and “Biomechanical Axis” Limitations (Exhibit A, Section H)
- “Anatomical Relief” Limitations (Exhibit A, Section B)
- “accommodates” and “accommodates an area of subchondral bone”
- “articular repair system”
- “portion”
- “predetermined”
- Additionally, based on Conformis’s position taken for the first time the day this disclosure was due that “reference an osteophyte” includes situations where there is no osteophyte at all because it was removed, “reference an osteophyte” also is indefinite, at least based on Conformis’s positions.

2. Lack of Written Description/Enablement

Based on the information available and under the apparent claim interpretations implicit in Conformis’s Infringement Contentions, certain of the Asserted Claims are invalid for failure to provide an adequate written description and/or enabling disclosure.

Conformis has only disclosed its positions regarding the purported support in the specification and priority applications for two groups of limitations, the “rotation angle”-related limitations of the ’304, ’161, and ’129 patents and the “reference an osteophyte” limitation of the ’482 patent. In both instances, the materials cited by Conformis do not support these limitations, and do not explain how to make and use the full scope of the claimed invention, at least as presently construed by Conformis. For most of the other limitations, Conformis’s positions remain unknown.

Even based on the deficient information provided by Conformis to date, moreover, the specifications also do not support the “predetermined” limitations, and do not explain how to make and use the claimed invention, at least as presently construed by Conformis.

IV. DOUBLE PATENTING

At least as applied and construed by Conformis in its infringement contentions, the '026 and '780 Patents are invalid for obviousness type double patenting, as improper attempts to extend the time to exclude granted by earlier-expiring patents assigned to Conformis. These include, for example, the '482 Patent and U.S. Patent Nos. 8,657,827 (“the '827 Patent”) and 8,105,330 (the '330 Patent”). Illustrative examples of how the '026 and '780 Patents are anticipated by, and obvious in view of, earlier-expiring Conformis patents are below. To the extent that any disclosure below does not expressly anticipate any aspect of the claims of the '026 Patent and '780 Patent, the claims were inherent or obvious in view of the disclosures below and/or the teachings of the prior art, including without limitation the prior art and motivations to modify and combine cited elsewhere in these invalidity contentions, the reference patents themselves, and the other asserted Conformis patents (to the extent that Conformis continues to maintain, as it does presently, that other asserted Conformis patents have earlier priority dates).

'026 Patent	'827 Patent claim 22
15. A system for joint arthroplasty, the system comprising:	1. A patient-specific surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, the instrument comprising:
52. A system for joint arthroplasty, the system comprising:	

<p>[15] a first template, the first template including:</p> <p>[52] a first template, the first template including:</p>	<p>1. A patient-specific surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, the instrument comprising:....”</p>
<p>[15] at least one surface for engaging a first articular surface of a joint,</p> <p>[52] at least one surface for engaging a first cartilage surface of a joint,</p>	<p>1. patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, the patient specific surface including cartilage information</p> <p>19. The surgical instrument of claim 13, wherein the corresponding portion of the diseased or damaged joint is a portion of the tibia of the knee joint of the patient and the guide defines a cutting or drilling path through a tibial plateau of the tibia.</p>
<p>[15] the at least one surface being substantially a negative of portions or all of the first articular surface;</p> <p>[52] the at least one surface being substantially a negative of portions of the first cartilage surface;</p>	<p>1. ...the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint,</p>
<p>[15] at least a portion of the at least one surface further including an anatomical relief; and</p> <p>[52] at least a portion of the surface further including an anatomical relief; and</p>	<p>1. wherein the patient-specific surface references the osteophyte</p>

<p>[15] at least one guide for directing movement of a surgical instrument; and wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.</p> <p>[52] at least one guide for directing movement of a surgical instrument; and wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis.</p>	<p>1. a guide sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool</p> <p>22. The surgical instrument of claim 19, wherein the cutting or drilling path is at a predetermined orientation relative to at least one of a mechanical axis and an anatomic axis of the knee joint of the patient.</p>
<p>16. The system of claim 15, wherein the at least one guide includes at least one of the features selected from the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting plane.</p>	<p>19. The surgical instrument of claim 13, wherein the corresponding portion of the diseased or damaged joint is a portion of the tibia of the knee joint of the patient and the guide defines a cutting or drilling path through a tibial plateau of the tibia.</p>
<p>23. The system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the first articular surface of the joint.</p>	<p>1. wherein the patient-specific surface references the osteophyte</p>

<p>'026 Patent</p>	<p>'827 Patent claim 53</p>
<p>15. A system for joint arthroplasty, the system comprising:</p>	<p>53. A surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, comprising:</p>

52. A system for joint arthroplasty, the system comprising:	
[15] a first template, the first template including: [52] a first template, the first template including:	53. ...a cutting block having a patient-specific surface and a guide...
[15] at least one surface for engaging a first articular surface of a joint, [52] at least one surface for engaging a first cartilage surface of a joint,	53. the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,
[15] the at least one surface being substantially a negative of portions or all of the first articular surface; [52] the at least one surface being substantially a negative of portions of the first cartilage surface;	53. the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint, wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint;
[15] at least a portion of the at least one surface further including an anatomical relief; and [52] at least a portion of the surface further including an anatomical relief; and	53. wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint;

<p>[15] at least one guide for directing movement of a surgical instrument; and wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.</p> <p>[52] at least one guide for directing movement of a surgical instrument; and wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis.</p>	<p>53. the guide being sized and shaped to accommodate a surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.</p>
<p>16. The system of claim 15, wherein the at least one guide includes at least one of the features selected from the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting plane.</p>	<p>53. a cutting block having a patient-specific surface and a guide;</p>
<p>23. The system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the first articular surface of the joint.</p>	<p>53. the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint, wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint;</p>

'026 Patent	'827 Patent claim 63
<p>15. A system for joint arthroplasty, the system comprising:</p> <p>52. A system for joint arthroplasty, the system comprising:</p>	<p>59. A surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, comprising:</p>
<p>[15] a first template, the first template including:</p> <p>[52] a first template, the first template including:</p>	<p>59. ...a block having a patient-specific surface and a guide...</p>
<p>[15] at least one surface for engaging a first articular surface of a joint,</p> <p>[52] at least one surface for engaging a first cartilage surface of a joint,</p>	<p>59. the patient-specific surface having at least a portion configured to have a shape that is substantially a negative of a corresponding surface portion of the diseased or damaged joint, wherein the corresponding surface portion includes cartilage and an osteophyte...</p> <p>63. The surgical instrument of claim 59, wherein the patient-specific surface is configured to engage at least a portion of the osteophyte of the diseased or damaged joint.</p>
<p>[15] the at least one surface being substantially a negative of portions or all of the first articular surface;</p> <p>[52] the at least one surface being substantially a negative of portions of the first cartilage surface;</p>	<p>59. the patient-specific surface having at least a portion configured to have a shape that is substantially a negative of a corresponding surface portion of the diseased or damaged joint, wherein the corresponding surface portion includes cartilage and an osteophyte, wherein the patient-specific surface is configured to reference the osteophyte</p> <p>63. The surgical instrument of claim 59, wherein the patient-specific surface is configured to engage at least a portion of the osteophyte of the diseased or damaged joint.</p>

<p>[15] at least a portion of the at least one surface further including an anatomical relief; and</p> <p>[52] at least a portion of the surface further including an anatomical relief; and</p>	<p>59. wherein the patient-specific surface is configured to reference the osteophyte;</p> <p>63. The surgical instrument of claim 59, wherein the patient-specific surface is configured to engage at least a portion of the osteophyte of the diseased or damaged joint.</p>
<p>[15] at least one guide for directing movement of a surgical instrument; and wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.</p> <p>[52] at least one guide for directing movement of a surgical instrument; and wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis.</p>	<p>59. the guide having a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool when the patient-specific surface is placed against the corresponding surface portion of the diseased or damaged joint such that the guide has a predetermined alignment relative to an anatomical or biomechanical axis of the diseased or damaged joint.</p>
<p>16. The system of claim 15, wherein the at least one guide includes at least one of the features selected from the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting plane.</p>	<p>59. a block having a patient-specific surface and a guide sized and shaped to accommodate a surgical tool,</p>
<p>23. The system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the</p>	<p>59. the patient-specific surface having at least a portion configured to have a shape that is substantially a negative of a corresponding surface portion of the diseased or damaged joint, wherein the corresponding surface portion includes cartilage and</p>

first articular surface of the joint.	an osteophyte, wherein the patient-specific surface is configured to reference the osteophyte;
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'026 Patent	'330 Patent, claim 100 and 101
15. A system for joint arthroplasty, the system comprising: 52. A system for joint arthroplasty, the system comprising:	56. A surgical tool for use in surgically repairing a joint of a patient, comprising:
[15] a first template, the first template including: [52] a first template, the first template including:	56. A surgical tool for use in surgically repairing a joint of a patient, comprising: a cutting block having a patient-specific surface and a guide;
[15] at least one surface for engaging a first articular surface of a joint, [52] at least one surface for engaging a first cartilage surface of a joint,	56. the patient-specific surface having a first portion has a shape that is substantially a negative of a corresponding portion of an articular surface of the joint... engaged and aligned with the corresponding portion of the articular surface Claim 100: The surgical tool of claim 56, wherein the tool is configured to be oriented along a mechanical axis of the joint when the patient-specific surface is placed against and aligned with the cartilage surface. Claim 101: The surgical tool of claim 75, wherein the tool is configured to be oriented along an anatomical axis of the joint when the patient-specific surface is placed against and aligned with the cartilage surface

<p>[15] the at least one surface being substantially a negative of portions or all of the first articular surface;</p> <p>[52] the at least one surface being substantially a negative of portions of the first cartilage surface;</p>	<p>56. the patient-specific surface having a first portion has a shape that is substantially a negative of a corresponding portion of an articular surface of the joint</p> <p>Claim 100: The surgical tool of claim 56, wherein the tool is configured to be oriented along a mechanical axis of the joint when the patient-specific surface is placed against and aligned with the cartilage surface.</p> <p>Claim 101: The surgical tool of claim 75, wherein the tool is configured to be oriented along an anatomical axis of the joint when the patient-specific surface is placed against and aligned with the cartilage surface</p>
<p>[15] at least a portion of the at least one surface further including an anatomical relief; and</p> <p>[52] at least a portion of the surface further including an anatomical relief; and</p>	<p>56. a second portion that is configured to substantially avoid contact with one or more osteophytes of the joint when the first portion is engaged and aligned with the corresponding portion of the articular surface;</p>
<p>[15] at least one guide for directing movement of a surgical instrument;</p> <p>and wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.</p> <p>[52] at least one guide for directing movement of a surgical instrument; and wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis.</p>	<p>56...the guide being sized to accommodate a cutting tool and have a position and orientation relative to the patient-specific surface to provide a predetermined drilling or cutting path for the cutting tool ...</p> <p>100. The surgical tool of claim 56, wherein the tool is configured to be oriented along a mechanical axis of the joint when the patient-specific surface is placed against and aligned with the cartilage surface.</p> <p>101. The surgical tool of claim 75, wherein the tool is configured to be oriented along an anatomical axis of the joint when the patient-specific surface is placed against and aligned with the cartilage surface</p>

16. The system of claim 15, wherein the at least one guide includes at least one of the features selected from the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting plane.	56. the guide being sized to accommodate a cutting tool <i>See also</i> claim 72: the guide is configured to define a cutting path through a femoral surface
23. The system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the first articular surface of the joint.	56. a second portion that is configured to substantially avoid contact with one or more osteophytes of the joint when the first portion is engaged and aligned with the corresponding portion of the articular surface;

'780 Patent	'482 Patent claim 2 and 3
1[pre] A system for joint arthroplasty for repairing a joint of a patient, the system comprising: 3. A method of joint arthroplasty using the system of claim 1, comprising:	1. A joint arthroplasty system for repairing a diseased or damaged joint of a patient comprising
[1] a first template, the first template including:	1. a patient-specific surgical instrument configured to facilitate the placement of the implant into the diseased or damaged joint, the instrument comprising

<p>[1a] a contact surface for engaging a first articular surface of the joint of the patient,</p> <p>[3a] engaging the contact surface of the first template with the first articular surface of the joint, and</p>	<p>1. a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, the patient specific surface including cartilage information derived from image data of the diseased or damaged joint,</p>
<p>[1b] the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface;</p>	<p>1. the patient specific surface including cartilage information derived from image data of the diseased or damaged joint,</p>
<p>[1c] at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface; and</p> <p>5. The system of claim 1, wherein the anatomic relief accommodates one or more osteophytes of the joint</p>	<p>1. wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and</p> <p>2. The system of claim 1, wherein the patient-specific surgical instrument is configured such that the patient-specific surface extends over but does not engage a second osteophyte of the diseased or damaged joint when the patient specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.</p> <p>3. The system of claim 1, wherein the patient-specific surgical instrument is configured such that the patient-specific surface extends over but substantially does not engage a second osteophyte of the diseased or damaged joint when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.</p>

<p>[1d] at least one guide for directing movement of a surgical instrument;</p> <p>and wherein the guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis associated with the joint of the patient.</p> <p>[3b] moving the surgical instrument with the at least one guide to prepare the joint of the patient for receiving an implant.</p>	<p>a guide sized and shaped to accommodate a surgical tool,</p> <p>wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool</p>
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'780 Patent	'827 Patent claim 2 and 3
<p>1[pre] A system for joint arthroplasty for repairing a joint of a patient, the system comprising:</p> <p>3. A method of joint arthroplasty using the system of claim 1, comprising:</p>	<p>1. A patient-specific surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, the instrument comprising:</p>
<p>[1] a first template, the first template including:</p>	<p>1. A patient-specific surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, the instrument comprising</p>

<p>[1a] a contact surface for engaging a first articular surface of the joint of the patient,</p> <p>[3a] engaging the contact surface of the first template with the first articular surface of the joint, and</p>	<p>1. a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, the patient specific surface including cartilage information derived from image data of the diseased or damaged joint,</p>
<p>[1b] the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface;</p>	<p>1. the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint</p>
<p>[1c] at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface; and</p> <p>5. The system of claim 1, wherein the anatomic relief accommodates one or more osteophytes of the joint</p>	<p>1. wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and</p> <p>2. The surgical instrument of claim 1, wherein the patient-specific surgical instrument is configured such that the patient-specific surface extends over but does not engage a second osteophyte of the diseased or damaged joint when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.</p> <p>3. The surgical instrument of claim 1, wherein the patient-specific surgical instrument is configured such that the patient-specific surface extends over but substantially does not engage a second osteophyte of the diseased or damaged joint when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint.</p>
<p>[1d] at least one guide for directing movement of a surgical instrument;</p> <p>and wherein the guide has a predetermined orientation relative to one</p>	<p>a guide sized and shaped to accommodate a surgical tool,</p> <p>wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool</p>

of an anatomical and a biomechanical axis associated with the joint of the patient. [3b] moving the surgical instrument with the at least one guide to prepare the joint of the patient for receiving an implant.	<i>See also</i> Claim 22: “The surgical instrument of claim 19, wherein the cutting or drilling path is at a predetermined orientation relative to at least one of a mechanical axis and an anatomic axis of the knee joint of the patient.”
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V. ACCOMPANYING DOCUMENT PRODUCTION

Defendants have produced and/or made available for inspection—or will be producing or making available for inspection—a copy of each prior art reference identified in these preliminary Invalidity Contentions.

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Dated: August 12, 2022

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CERTIFICATE OF SERVICE

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Exhibit 2

Invalidity of U.S. Patent No. 8,623,026 in view of U.S. Publication No. 2004/0236424 to Aaron Berez et al.

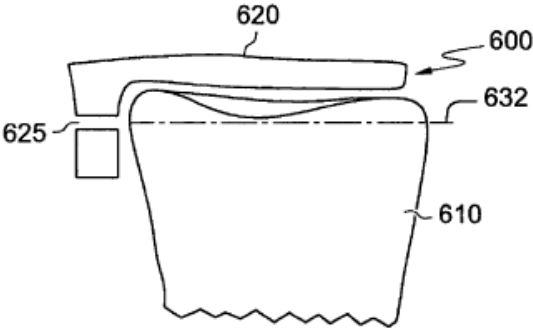
The following chart provides an analysis of the invalidity of claims 15, 16, 23, and 52 of U.S. Patent No. 8,623,026 (“the ’026 Patent”) over U.S. Publication No. 2004/0236424 to Aaron Berez et al. (“Berez”). Berez was filed on November 25, 2003 and published November 25, 2004. Berez qualifies as prior art to the ’026 Patent under at least 35 U.S.C. § 102 (a), (b), (e) (pre-AIA). Berez anticipates and renders obvious each claim of the ’026 Patent, as explained in the chart below and in the contentions. The citations below are not intended to be limiting and are for the purpose of illustrating Defendants’ invalidity theories only. Defendants reserve the right to rely on all parts of Berez and disclosures incorporated therein, whether expressly cited below or not.

In addition and in the alternative, Berez renders all claims obvious in combination with one or more of the prior art references identified in Defendants’ Invalidity Contentions. It would have been obvious to combine Berez with any one or more of these other prior art references, which are analogous art, at least because such combinations: combine prior art elements according to known methods to yield predictable results; are a simple substitution of one known element for another to obtain predictable results; use known techniques to improve similar devices, methods, or products in the same way; apply a known technique to a known device, method, or product ready for improvement to yield predictable results; are obvious to try, including because they choose from a finite number of identified, predictable solutions with a reasonable expectation of success; use a known work in one field of endeavor to prompt variations of it for use in either the same field or a different one based on design incentives or other market forces since the variations are predictable to one of ordinary skill in the art; and contain some teaching, suggestion, or motivation that would have led one of ordinary skill in the art to modify or combine Berez to arrive at the claimed invention. Defendants have provided certain exemplary combinations for illustration. However, these combinations are merely exemplary and non-limiting. For avoidance of doubt, Defendants also rely on combinations with the other references described in Exhibit A and in the other claim charts. Additionally, ConforMIS’s disclosures regarding the priority dates of its own patents and patent applications is unclear and deficient. Defendants reserve the right to use any of the asserted patents and the applications cited therein as prior art to other asserted patents.

ConforMIS has applied overly broad constructions of various limitations of the asserted claims in its complaint and in its infringement contentions. This claim chart takes into account ConforMIS’s overly broad construction of the claim limitations, including the constructions implicit in its complaint and infringement contentions. Any assertion that a particular limitation is disclosed by a prior art reference or references may be based in whole or in part on ConforMIS’s apparent constructions and is not intended to be, and is not, an admission that such constructions are supportable or proper. Rather, any construction broad enough to allegedly read on any accused method or structure would necessarily read on the prior art, further confirming that the claims are invalid.

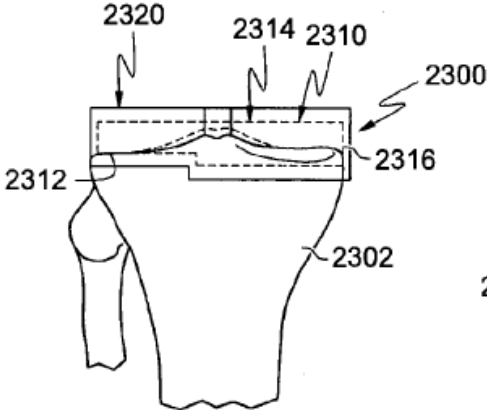
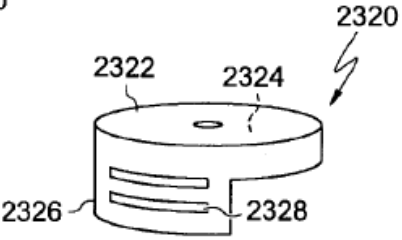
Claims of US 8,623,026	Invalidity Contentions
<p>[15-pre] A system for joint arthroplasty, the system comprising:</p>	<p>To the extent that the preamble is limiting, Berez discloses (explicitly, implicitly, and inherently) and also renders obvious a system for joint arthroplasty, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0291] <ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee

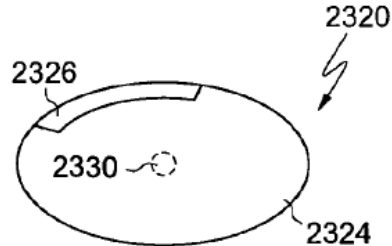
Claims of US 8,623,026	Invalidity Contentions
	<p>arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.</p> <ul style="list-style-type: none"> • [0292] <ul style="list-style-type: none"> ○ Thus, surgical tools described herein can also be designed and used to control drill alignment, depth and width, for example when preparing a site to receive an implant. For example, the tools described herein, which typically conform to the joint surface, can provide for improved drill alignment and more accurate placement of any implant. • [0068] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. 24B depicts, in crosssection, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone. • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the

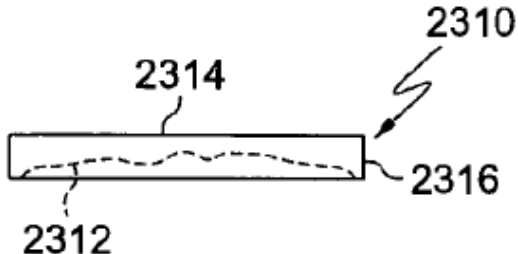
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="741 272 1822 342">proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone.</p> <ul style="list-style-type: none"><li data-bbox="598 386 793 415">• Figure 24A<ul style="list-style-type: none"><li data-bbox="695 464 711 483">○<li data-bbox="598 987 793 1016">• Figure 24B

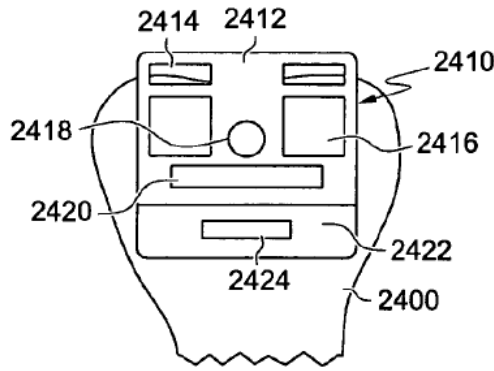
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730"> </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 836 735 876">• [0294] <li data-bbox="693 909 1858 1209">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface. <li data-bbox="598 1242 735 1282">• [0069]

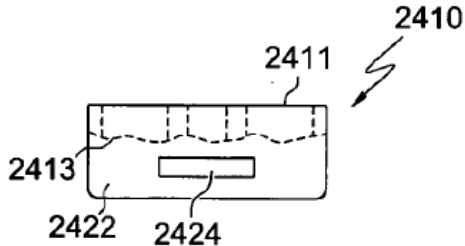
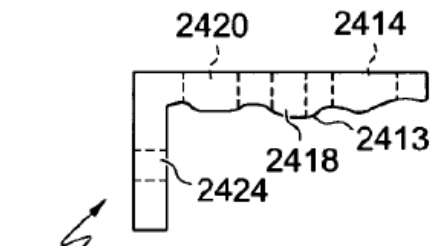
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ FIGS. 25A-Q illustrate tibial cutting blocks and molds used to create a surface perpendicular to the anatomic axis for receiving the tibial portion of a knee implant. • [0295] <ul style="list-style-type: none"> ○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. • [0296] <ul style="list-style-type: none"> ○ The reusable exterior piece has a superior surface 2322 and an inferior surface 2324 that mates with the first piece 2310. The reusable exterior piece 2320 includes cutting guides 2328, to assist the surgeon in performing the tibial surface cut described above. As shown herein a plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the tibial cut. • [0300] <ul style="list-style-type: none"> ○ A guide plate 2326 is provided that extends along the side of at least a portion of the exterior piece 2320. The guide plate 2326 provides one or more slots or guides 2328 through which a saw blade can be inserted to achieve the cut desired of the tibial surface. Additionally, the slot, or guide, can be configured so that the saw blade cuts at a line perpendicular to the mechanical axis, or so that it cuts at a line that is

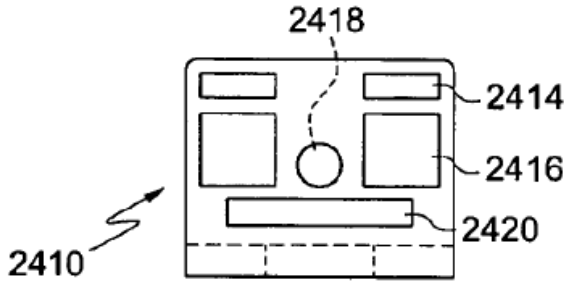
Claims of US 8,623,026	Invalidity Contentions
	<p>perpendicular to the mechanical axis, but has a 4-7° slope in the sagittal plane to match the normal slope of the tibia.</p> <ul style="list-style-type: none"> • Figures 25A & 25B <ul style="list-style-type: none"> ○  ○  <p>FIG. 25A</p> <p>FIG. 25B</p> <ul style="list-style-type: none"> • [0301] <ul style="list-style-type: none"> ○ Optionally, a central bore 2330 can be provided that, for example, enables a drill to ream a hole into the bone for the stem of the tibial component of the knee implant. • Figure 25C

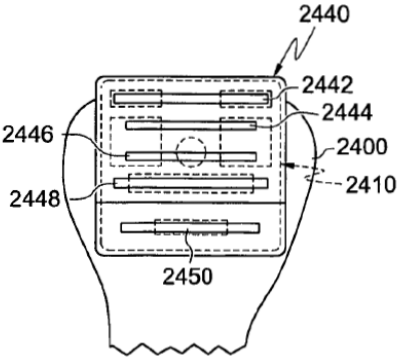
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="772 349 1161 592">  </div> <p data-bbox="840 617 1029 665">FIG. 25C</p> <ul style="list-style-type: none"> <li data-bbox="598 747 1858 925"> <p>• [0297]</p> <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. <li data-bbox="598 966 1858 1185"> <p>• [0298]</p> <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci. <li data-bbox="598 1226 787 1258"> <p>• Figure 25E</p>

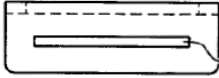
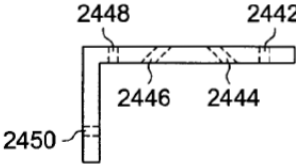
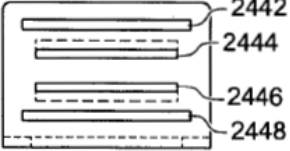
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 341 1270 592">  </div> <p data-bbox="840 633 1102 698">FIG. 25E</p> <ul style="list-style-type: none"> <li data-bbox="598 763 735 803">• [0070] <ul style="list-style-type: none"> <li data-bbox="693 836 1795 909">○ FIGS. 26A-O illustrate femur cutting blocks and molds used to create a surface for receiving the femoral portion of a knee implant. <li data-bbox="598 950 735 990">• [0312] <ul style="list-style-type: none"> <li data-bbox="693 1023 1816 1128">○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. <li data-bbox="598 1169 735 1209">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 1242 1837 1347">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures

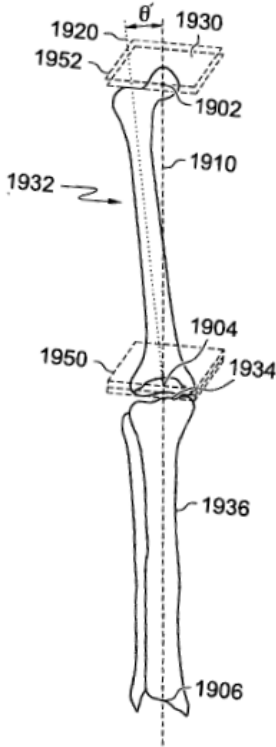
Claims of US 8,623,026	Invalidity Contentions
	<p>2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> Fig. 26A <ul style="list-style-type: none">  [0314]-[0315]

Claims of US 8,623,026	Invalidity Contentions
	<p>○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur.</p> <p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>FIG. 26B</p> </div> <div style="text-align: center;">  <p>FIG. 26C</p> </div> </div> <ul style="list-style-type: none"> • [0316]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ FIG. 26D illustrates a top view of the first portion 2410. The bottom of the illustration corresponds to an anterior location relative to the knee joint. From the top view, each of the apertures is illustrated as described above. As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention. • Figure 26D <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26D</p> <ul style="list-style-type: none"> • [0317]-[0318] <ul style="list-style-type: none"> ○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example,

Claims of US 8,623,026	Invalidity Contentions
	<p>at a 45° angle. Other angles are also possible without departing from the scope of the invention.</p> <p>As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer.</p> <ul style="list-style-type: none"> • Figure 26E <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26E</p> <ul style="list-style-type: none"> • [0319] <ul style="list-style-type: none"> ○ FIG. 26F illustrates a side view of the second, exterior, cutting block portion 2440. From the side view a single aperture 2450 is provided to access the femur cut. FIG. 26G is another side view of the second, exterior, portion 2440 showing the location and relative angles of the rectangular grooves. As evidenced from this view, the orientation of the grooves 2442, 2448 and 2450 is perpendicular to at least one surface of the second, exterior, portion 2440. The orientation of the grooves 2444, 2446 is at an angle

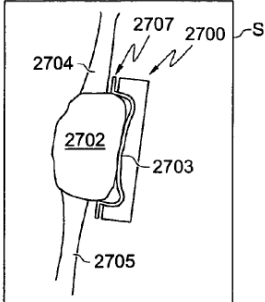
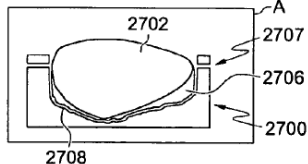
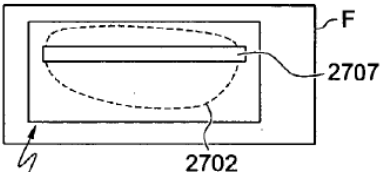
Claims of US 8,623,026	Invalidity Contentions
	<p>that is not perpendicular to at least one surface of the second, exterior portion 2440. These grooves (2444, 2446) facilitate making the angled chamfer cuts to the femur. FIG. 26H is a top view of the second, exterior portion 2440. As will be appreciated by those of skill in the art, the location and orientation of the grooves will change depending upon the design of the femoral implant and the shape required of the femur to communicate with the implant.</p> <ul style="list-style-type: none"> • Figures 26F & 26G <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end; margin-top: 20px;"> <div style="text-align: center;">  <p>FIG. 26F</p> </div> <div style="text-align: center;">  <p>FIG. 26G</p> </div> <div style="text-align: center;">  <p>FIG. 26H</p> </div> </div> <ul style="list-style-type: none"> • [0253] <ul style="list-style-type: none"> ○ Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee. • [0065] <ul style="list-style-type: none"> ○ FIG. 21A illustrates a femur, tibia and fibula along with the mechanical and anatomic axes. FIGS. 21B-E illustrate the tibia with the anatomic and mechanical axis used to

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	<p>create a cutting plane along with a cut femur and tibia. FIG. 21F illustrates the proximal end of the femur including the head of the femur.</p> <ul style="list-style-type: none"> • Figure 21A <ul style="list-style-type: none"> ○  <ul style="list-style-type: none"> • [0254]

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	<ul style="list-style-type: none"> ○ As shown in FIG. 21A, the center of the hip 1902 (located at the head 1930 of the femur 1932), the center of the knee 1904 (located at the notch where the intercondular tubercle 1934 of the tibia 1936 meet the femur) and ankle 1906 lie approximately in a straight line 1910 which defines the mechanical axis of the lower extremity. The anatomic axis 1920 aligns 5-7° offset 8 from the mechanical axis in the valgus, or outward, direction. • [0255] <ul style="list-style-type: none"> ○ The long axis of the tibia 1936 is collinear with the mechanical axis of the lower extremity 1910. From a three-dimensional perspective, the lower extremity of the body ideally functions within a single plane known as the median anterior-posterior plane (MAP-plane) throughout the flexion-extension arc. In order to accomplish this, the femoral head 1930, the mechanical axis of the femur, the patellar groove, the intercondylar notch, the patellar articular crest, the tibia and the ankle remain within the MAP-plane during the flexion-extension movement. During movement, the tibia rotates as the knee flexes and extends in the epicondylar axis which is perpendicular to the MAP-plane. • [0257] <ul style="list-style-type: none"> ○ With disease and malfunction of the knee, alignment of the anatomic axis is altered. Performing a total knee arthroplasty is one solution for correcting a diseased knee. Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee. The resections should be made to enable the installed artificial knee to achieve flexion-extension movement within the MAP-plane and to optimize the patient's anatomical and mechanical axis of the lower extremity.

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	<ul style="list-style-type: none"> • [0258] <ul style="list-style-type: none"> ○ First, the tibia 1930 is resected to create a flat surface to accept the tibial component of the implant. In most cases, the tibial surface is resected perpendicular to the long axis of the tibia in the coronal plane, but is typically sloped 4-7° posteriorly in the sagittal plane to match the normal slope of the tibia. As will be appreciated by those of skill in the art, the sagittal slope can be 0° where the device to be implanted does not require a sloped tibial cut. The resection line 1958 is perpendicular to the mechanical axis 1910, but the angle between the resection line and the surface plane of the plateau 1960 varies depending on the amount of damage to the knee. • [0259] <ul style="list-style-type: none"> ○ FIGS. 21B-D illustrate an anterior view of a resection of an anatomically normal tibial component, a tibial component in a varus knee, and a tibial component in a valgus knee, respectively. In each figure, the mechanical axis 1910 extends vertically through the bone and the resection line 1958 is perpendicular to the mechanical axis 1910 in the coronal plane, varying from the surface line formed by the joint depending on the amount of damage to the joint. FIG. 21B illustrates a normal knee wherein the line corresponding to the surface of the joint 1960 is parallel to the resection line 1958. FIG. 21C illustrates a varus knee wherein the line corresponding to the surface of the joint 1960 is not parallel to the resection line 1958. FIG. 21D illustrates a valgus knee wherein the line corresponding to the surface of the joint 1960 is not parallel to the resection line 1958. • [0260] <ul style="list-style-type: none"> ○ Once the tibial surface has been prepared, the surgeon turns to preparing the femoral condyle.

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	<ul style="list-style-type: none"> • [0261] <ul style="list-style-type: none"> ○ The plateau of the femur 1970 is resected to provide flat surfaces that communicate with the interior of the femoral prosthesis. The cuts made to the femur are based on the overall height of the gap to be created between the tibia and the femur. Typically, a 20 mm gap is desirable to provide the implanted prosthesis adequate room to achieve full range of motion. The bone is resected at a 5-7° angle valgus to the mechanical axis of the femur. Resected surface 1972 forms a flat plane with an angular relationship to adjoining surfaces 1974, 1976. The angle θ', θ'' between the surfaces 1972-1974, and 1972-1976 varies according to the design of the implant. • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A. The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702.

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	<ul style="list-style-type: none"> • Figures 27A, 27B & 27C <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 27A</p> ○  <p style="text-align: center;">FIG. 27B</p> ○  <p style="text-align: center;">FIG. 27C</p> • [0333] <ul style="list-style-type: none"> ○ FIG. 28B illustrates a top view of the cutting block system 2520. The cutting block system 2520 includes an interior, patient specific, molded section 2524 and an exterior cutting block surface 2522. The interior, patient specific, molded section 2524 can include a canal 2526 to facilitate placing the interior section 2524 over the neck of the femur. As will be appreciated by those of skill in the art, the width of the canal will vary depending upon the rigidity of the material used to make the interior molded section. The exterior cutting block surface 2522 is configured to fit snugly around the interior section. Additional structures can be provided, similar to those described above with respect to the knee cutting block system, that control movement of the exterior cutting block 2524 relative to interior mold section 2522, as will be appreciated by those of skill in the art. Where the interior section 2524 encompasses all or part of the femoral neck, the cutting block system can be configured such that it aids in removal of the femoral head once the cut has been made by, for example, providing a handle 2501.

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	<ul style="list-style-type: none"> • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • [0266] <ul style="list-style-type: none"> ○ Mechanical devices can be used for surgical assistance (e.g., surgical tools), for example using gels, molds, plastics or metal. One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be utilized to either shape the device, e.g. using a CAD/CAM technique, to be adapted to a patient's articular anatomy or, alternatively, to select a typically pre-made device that has a good fit with a patient's articular anatomy. The device can have a surface and shape that will match all or portions of the articular or bone surface and shape, e.g.

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	<p>similar to a "mirror image." The device can include apertures, slots and/or holes to accommodate surgical instruments such as drills, reamers, curettes, k-wires, screws and saws.</p> <ul style="list-style-type: none"> • [0267] <ul style="list-style-type: none"> ○ Typically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general instrument orientation for subsequent placement of an articular repair system or for facilitating placement of the articular repair system. Moreover, the device can be designed so that the depth of the drill, reamer or other surgical instrument can be controlled, e.g., the drill cannot go any deeper into the tissue than defined by the device, and the size of the hole in the block can be designed to essentially match the size of the implant. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. Alternatively, the openings in the device can be made larger than needed to accommodate these instruments. The device can also be configured to conform to the articular shape. The apertures, or openings, provided can be wide enough to allow for varying the position or angle of the surgical instrument, e.g., reamers, saws, drills, curettes and other surgical instruments. An instrument guide, typically comprised of a relatively hard material, can then be applied to the device. The device helps orient the instrument guide relative to the three-dimensional anatomy of the joint. • [0274] <ul style="list-style-type: none"> ○ One or more molds can be used during the surgery. For example, in the hip, a mold can be initially applied to the proximal femur that closely approximates the 3D anatomy prior to the resection of the femoral head. The mold can include an opening to accommodate a saw (see FIGS. 28-29). The opening is positioned to achieve an optimally placed surgical cut for subsequent reaming and placement of the prosthesis.

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	<p>A second mold can then be applied to the proximal femur after the surgical cut has been made. The second mold can be useful for guiding the direction of a reamer prior to placement of the prosthesis. As can be seen in this, as well as in other examples, molds can be made for joints prior to any surgical intervention. However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.</p> <ul style="list-style-type: none"> • [0277] <ul style="list-style-type: none"> ○ In another embodiment, a frame can be applied to the bone or the cartilage in areas other than the diseased bone or cartilage. The frame can include holders and guides for surgical instruments. The frame can be attached to one or preferably more previously defined anatomic reference points. Alternatively, the position of the frame can be cross-registered relative to one, or more, anatomic landmarks, using an imaging test or intraoperative measurement, for example one or more fluoroscopic images acquired intraoperatively. One or more electronic images or intraoperative measurements including using mechanical devices can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to move one or more of the holders or guides for surgical instruments. Typically, a position will be chosen that will result in a surgically or anatomically desirable cut plane or drill hole orientation for subsequent placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • [0278]

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	<ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0287] <ul style="list-style-type: none"> ○ The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical tool can include one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface facing the surgical tool and, accordingly, will form a mirror image impression of the surface upon hardening, thereby recreating a normal or near normal articular surface. In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint. • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been

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	<p>measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141.</p> <ul style="list-style-type: none">• Figure 23

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	<p>○</p> <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] -- Optional 2101 --> 2100 2100 --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 -- Optional 2121 --> 2120 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 -- Optional 2131 --> 2130 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 -- Optional 2133 --> 2132 2134 -- Optional 2135 --> 2134 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 -- Optional 2141 --> 2140 2140 --> 2142((Perform Implantation 2142)) 2102 --> 2100 </pre> <ul style="list-style-type: none"> • [0166]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In another embodiment, a balloon such as that shown in FIGS. 11A-E, can be used as the implantation device. Different balloon shapes and sizes can be made available. A detailed description of all possible shapes and sizes for the balloons is not included to avoid obscuring the invention, but would be apparent to those of skill in the art. Where a balloon is used, it can be inserted into a joint and inflated. The size, height, shape and position of the balloon can be evaluated arthroscopically or via an open incision or using, for example, an imaging test relative to the articular surface and the other articular strictures. Range of motion testing can be performed in order to ensure adequate size, shape and position of the device during the full range of motion. • [0167] ○ After insertion, the balloon can be slowly injected with, for example, a self-hardening material, or material that hardens upon activation. Suitable materials are described below and would be apparent to those of skill in the art. Typically, upon injection, the material is in a fluid or semi-fluid state. The material expands the balloon as it is injected which results in the balloon taking on the shape of the articular surface, for example as shown in FIG. 11A, and other articular structures such that it fills the defect. • Figures 11A and 11B

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	<p>○</p> <div data-bbox="751 316 1617 771"> <p>FIG. 11A FIG. 11B</p> </div> <ul style="list-style-type: none"> • [0178] <ul style="list-style-type: none"> ○ Differences in wall thickness, pressure tolerances and expandability of balloons can also be used to influence the resulting shape of the injected material. • [0179] <ul style="list-style-type: none"> ○ The results of using inflation devices, or balloons, with differing wall thicknesses or pressure tolerances is shown in FIGS. 12A-F. As shown in FIG. 12A the balloon 1200 has an upper surface 1210 and a lower surface 1212 along with a proximal end 1214 and a distal end 1216. The relative pressure tolerance of the balloon or inflation device 1200 is lower on the lower surface 1212 than the upper surface 1210. As a result, the upper surface of the balloon 1210 has a relatively flat configuration relative to its corresponding joint surface while the lower surface 1212 has a relatively conforming shape relative to its corresponding joint surface.

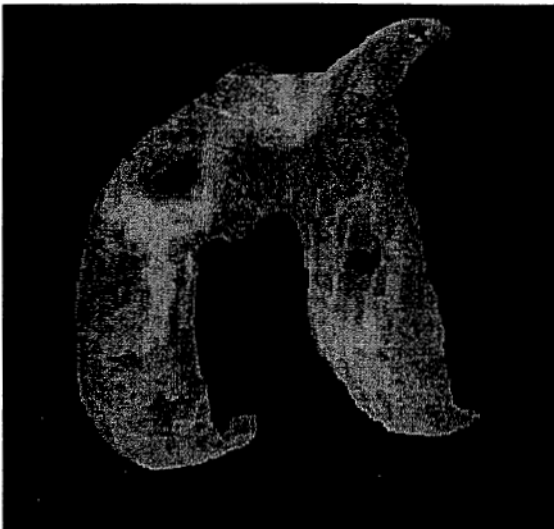
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0180] <ul style="list-style-type: none"> ○ Turning now to FIG. 12B, the inflation device used 1220 has a relatively constant pressure tolerance that is relatively high which results in both the upper surface 1210 and the lower surface 1212 having relatively flat configurations relative to each of its corresponding joint surfaces, regardless of the joint surface anatomy. • [0181] <ul style="list-style-type: none"> ○ FIG. 12C illustrates a balloon 1230 having a low inflation pressure at its proximal 1214 and distal 1216 ends, with a higher inflation pressure at a central region 1218. The result of this configuration is that when the balloon is inflated, the proximal and distal ends inflate to a greater profile (e.g., height) than the central region. The inflation pressure of the central region, although higher than the proximal and distal ends, can be set such that the central region has a relatively flat configuration relative to the corresponding joint surfaces, as shown, or can be configured to achieve the result shown in FIG. 12A. • [0056] <ul style="list-style-type: none"> ○ FIGS. 12A-E illustrate a variety of cross-sectional shapes achieved using balloons with variable wall thicknesses or material compositions. In FIG. 12A the inflation device enables the implant to achieve a surface conforming to the irregularities of the joint surface. In FIG. 12B the inflation device enables the implant to achieve a surface that sits above the irregular joint surface; FIG. 12C illustrates a device formed where a central portion of the device sits above the joint surface irregularities while the proximal and distal ends illustrated form a lateral abutting surface to the joint defects. FIG. 12D illustrates a device formed using a first inflation device within a second inflation device, with an exterior configuration similar to that shown in FIG. 12A;

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	<p>while FIG. 12E illustrates an alternative device formed using at least two different inflation devices having an exterior shape similar to the device shown in FIG. 12C.</p> <ul style="list-style-type: none"> • Figures 12A-E <ul style="list-style-type: none"> ○ <div style="text-align: center;"> </div> <ul style="list-style-type: none"> • [0182] <ul style="list-style-type: none"> ○ As will be appreciated by those of skill in the art, any of these balloons can be configured to have varying properties resulting in portions of the wall being less rigid than other portions, within the same balloon, e.g. a rigid wall with high inflation

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	<p>pressures in the periphery and a less rigid wall with intermediate or low inflation pressures in the center. Where there is more than one thickness to the balloon, it could, for example, have less stiffness anteriorly; greater stiffness centrally, and less stiffness posteriorly. The wall thickness variability will enable the device to accommodate shape formation. Central thickness will help prevent the device from fully conforming to the irregular surface of the joint, which may be important where there are irregularities to the joint surface, such as bone spurs. Alternatively, if the central portion is of less stiffness than the anterior and posterior sections, the device would be configured to conform more closely to the shape of the joint surface, including any irregularities. The closer the device conforms to the joint shape, the more the device seats within the joint.</p> <ul style="list-style-type: none"> • Abstract <ul style="list-style-type: none"> ○ Disclosed herein are methods, compositions and tools for repairing articular surfaces repair materials and for repairing an articular surface. The articular surface repairs are customizable or highly selectable by patient and geared toward providing optimal fit and function. The surgical tools are designed to be customizable or highly selectable by patient to increase the speed, accuracy and simplicity of performing total or partial arthroplasty. • [0002] <ul style="list-style-type: none"> ○ The present invention relates to orthopedic methods, systems and prosthetic devices and more particularly relates to methods, systems and devices for articular resurfacing. The present invention also includes surgical molds designed to achieve optimal cut planes in a joint in preparation for installation of a joint implant. • [0034]

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	<ul style="list-style-type: none"> ○ In any of the embodiments and aspects described herein, the joint can be a knee, shoulder, hip, vertebrae, elbow, ankle, wrist etc. • [0037] <ul style="list-style-type: none"> ○ In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool comprising one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). In certain embodiments, the tool comprises Lucite silastic and/or other polymers or suitable materials. The tool can be re-useable or single-use. The tool can be comprised of a single component or multiple components. In certain embodiments, the tool comprises an array of adjustable, closely spaced pins. In any embodiments described herein, the surgical tool can be designed to further comprise an aperture therein, for example one or more apertures having dimensions (e.g., diameter, depth, etc.) smaller or equal to one or more dimensions of the implant and/or one or more apertures adapted to receive one or more injectables. Any of the tools described herein can further include one or more curable (hardening) materials or compositions, for example that are injected through one or more apertures in the tool and which solidify to form an impression of the articular surface. • [0040] <ul style="list-style-type: none"> ○ Also disclosed is a customizable, or patient specific, implant configured for placement between joint surfaces formed by inserting a hollow device having an aperture and a lumen into a target joint, and injecting material into the hollow device to form an implant. • [0041]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ A customizable, or patient specific, implant configured for placement between joint surfaces is also disclosed wherein the implant is formed by inserting a retaining device that engages at least a portion of one joint surface in a joint and injecting material into an aperture of the retaining device to form an implant. • [0042] <ul style="list-style-type: none"> ○ The invention is also directed to tools. A is disclosed that tool comprises: a mold having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block. Another tool is disclosed that is formed at least partially in situ and comprises: a mold formed in situ using at least one of an inflatable hollow device or a retaining device to conform to the joint surface on at least one surface having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block. • [0046] <ul style="list-style-type: none"> ○ FIG. 2 is a color reproduction of a three-dimensional thickness map of the articular cartilage of the distal femur. Three-dimensional thickness maps can be generated, for example, from ultrasound, CT or MRI data. Dark holes within the substances of the cartilage indicate areas of full thickness cartilage loss. • Figure 2

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	<ul style="list-style-type: none">○ • [0079]<ul style="list-style-type: none">○ The methods and compositions described herein can be used to treat defects resulting from disease of the cartilage (e.g., osteoarthritis), bone damage, cartilage damage, trauma, and/or degeneration due to overuse or age. The invention allows, among other things, a health practitioner to evaluate and treat such defects. The size, volume and shape of the area of interest can include only the region of cartilage that has the defect, but preferably will also include contiguous parts of the cartilage surrounding the cartilage defect.• [0088]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Imaging can be used to determine the anatomical and biomechanical axes of an extremity associated with a joint. Suitable tests include, for example, an x-ray, or an x-ray combined with an MRI. Typically, anatomical landmarks are identified on the imaging test results (e.g., the x-ray film) and those landmarks are then utilized to directly or indirectly determine the desired axes. Thus, for example, if surgery is contemplated in a hip joint, knee joint, or ankle joint, an x-ray can be obtained. This x-ray can be a weightbearing film of the extremity, for example, a full-length leg film taken while the patient is standing. This film can be used to determine the femoral and tibial anatomical axes and to estimate the biomechanical axes. As will be appreciated by those of skill in the art, these processes for identifying, e.g., anatomical and biomechanical axis of the joint can be applied to other joints without departing from the scope of the invention. • [0089] <ul style="list-style-type: none"> ○ Anatomical and biomechanical axes can also be determined using other imaging modalities, including but not limited to, computed tomography and MRI. For example, a CT scan can be obtained through the hip joint, the knee joint, and the ankle joint. Optionally, the scan can be reformatted in the sagittal, coronal, or other planes. The CT images can then be utilized to identify anatomical landmarks and to determine the anatomical and biomechanical axes of the hip joint, knee joint, and/or ankle joint. Similarly, an MRI scan can be obtained for this purpose. For example, an MRI scan of the thigh and pelvic region can be obtained using a body coil or a torso phased array coil. A high resolution scan of the knee joint can be obtained using a dedicated extremity coil. A scan of the calf/tibia region and the ankle joint can be obtained again using a body coil or a torso phased array coil. Anatomical landmarks can be identified in each joint on these scans and the anatomical and biomechanical axes can be estimated using this information.

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	<ul style="list-style-type: none"> • [0091] <ul style="list-style-type: none"> ○ The biomechanical axis can be defined as the axis going from the center of the femoral head, between the condylar surfaces and through the ankle joint. • [0093] <ul style="list-style-type: none"> ○ The angles of the anatomical structures of the proximal and distal femur also show a certain variability level (i.e. standard deviation) comparable with the varus or valgus angle or the angle between the anatomical femoral axis and the biomechanical axis (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Slaten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering."Med. Eng. and Phys. 24 (2002) 617-622). Thus, a preferred approach for assessing the axes is based on CT scans of the hip, knee and ankle joint or femur rather than only of the knee region. • [0098] <ul style="list-style-type: none"> ○ Identification of landmarks of interest like the centroid of the tibial shaft, the ankle joint, the intercondylar notch and the centroid of the femoral head can be performed. The biomechanical axis can be defined as the line connecting the proximal and the distal centroids, i.e. the femoral head centroid, the tibial or ankle joint centroid. The position of the intercondylar notch can be used for evaluation of possible deviations, errors or deformations including varus and valgus deformity. • [0099] <ul style="list-style-type: none"> ○ In one embodiment, multiple imaging tests can be combined. For example, the anatomical and biomechanical axes can be estimated using a weight-bearing x-ray of

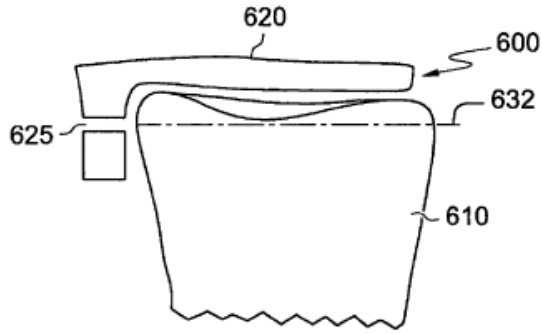
Claims of US 8,623,026	Invalidity Contentions
	<p>the extremity or portions of the extremity. The anatomical information derived in this fashion can then be combined with a CT or MRI scan of one or more joints, such as a hip, knee, or ankle joint. Landmarks seen on radiography can then, for example, be cross-referenced on the CT or MRI scan. Axis measurements performed on radiography can be subsequently applied to the CT or MRI scans or other imaging modalities. Similarly, the information obtained from a CT scan can be compared with that obtained with an MRI or ultrasound scan. In one embodiment, image fusion of different imaging modalities can be performed. For example, if surgery is contemplated in a knee joint, a full-length weight-bearing x-ray of the lower extremity can be obtained. This can be supplemented by a spiral CT scan, optionally with intra-articular contrast of the knee joint providing high resolution three-dimensional anatomical characterization of the knee anatomy even including the menisci and cartilage. This information, along with the axis information provided by the radiograph can be utilized to select or derive therapies, such as implants or surgical instruments.</p> <ul style="list-style-type: none"> • [0100] <ul style="list-style-type: none"> ○ In certain embodiments, it may be desirable to characterize the shape and dimension of intra-articular structures, including subchondral bone or the cartilage. This can be done using a CT scan, preferably a spiral CT scan of one or more joints. The spiral CT scan can optionally be performed using intra-articular contrast. Alternatively, an MRI scan can be performed. If CT is utilized, a full spiral scan, or a few selected slices, can be obtained through neighboring joints. Typically, a full spiral scan providing full three-dimensional characterization would be obtained in the joint for which therapy is contemplated. If implants, or molds, for surgical instruments are selected or shaped, using this scan, the subchondral bone shape can be accurately determined from the resultant image data. • [0101]

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	<ul style="list-style-type: none"> ○ Alternatively, however, the articular cartilage can be fully characterized by performing a spiral CT scan of the joint in the presence of intra-articular contrast or by performing an MRI scan using cartilage sensitive pulse sequences. • [0103] <ul style="list-style-type: none"> ○ Alternatively, or in addition to, non-invasive imaging techniques described above, measurements of the size of an area of diseased cartilage or an area of cartilage loss, measurements of cartilage thickness and/or curvature of cartilage or bone can be obtained intraoperatively during arthroscopy or open arthrotomy. Intraoperative measurements can, but need not, involve actual contact with one or more areas of the articular surfaces. • [0109] <ul style="list-style-type: none"> ○ Mechanical devices (e.g., probes) can also be used for intraoperative measurements, for example, deformable materials such as gels, molds, any hardening materials (e.g., materials that remain deformable until they are heated, cooled, or otherwise manipulated). See, e.g., WO 02/34310 to Dickson et al., published May 2, 2002. For example, a deformable gel can be applied to a femoral condyle. The side of the gel pointing towards the condyle can yield a negative impression of the surface contour of the condyle. The negative impression can then be used to determine the size of a defect, the depth of a defect and the curvature of the articular surface in and adjacent to a defect. This information can be used to select a therapy, e.g. an articular surface repair system. In another example, a hardening material can be applied to an articular surface, e.g. a femoral condyle or a tibial plateau. The hardening material can remain on the articular surface until hardening has occurred. The hardening material can then be removed from the articular surface. The side of the hardening material pointing towards the articular surface can yield a negative impression of the articular surface. The negative impression can then be used to determine the size of a defect, the depth of

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	<p>a defect and the curvature of the articular surface in and adjacent to a defect. This information can then be used to select a therapy, e.g. an articular surface repair system. In some embodiments, the hardening system can remain in place and form the actual articular surface repair system.</p> <ul style="list-style-type: none"> • [0136] <ul style="list-style-type: none"> ○ Using information on thickness and curvature of the cartilage, a physical model of the surfaces of the articular cartilage and of the underlying bone can be created. This physical model can be representative of a limited area within the joint or it can encompass the entire joint. For example, in the knee joint, the physical model can encompass only the medial or lateral femoral condyle, both femoral condyles and the notch region, the medial tibial plateau, the lateral tibial plateau, the entire tibial plateau, the medial patella, the lateral patella, the entire patella or the entire joint. The location of a diseased area of cartilage can be determined, for example using a 3D coordinate system or a 3D Euclidian distance as described in WO 02/22014. • <i>See also</i> Paragraph [0038], [0067], [0071]-[0073], [0084]-[0086], [0090], [0094]-[0096], [0110], [0168]-[0177], [0185]-[0186], [0265], [0280]-[0282], [302]-[311], [0320]-[0323], [0327]-[0332], [0334], [0337],; Figures 25D, 25F-25Q, 26I-26O, 27D-27G, 28A, 28E-F, 29D. <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

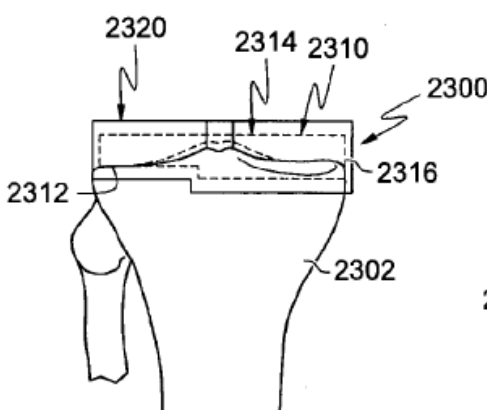
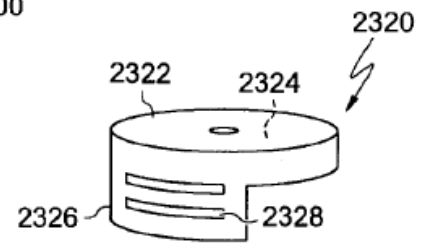
Claims of US 8,623,026	Invalidity Contentions
	<p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] (“The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>

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<p>[15.A] a first template, the first template including:</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious a first template, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0068] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. 24B depicts, in crosssection, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone. • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone. • Figure 24A

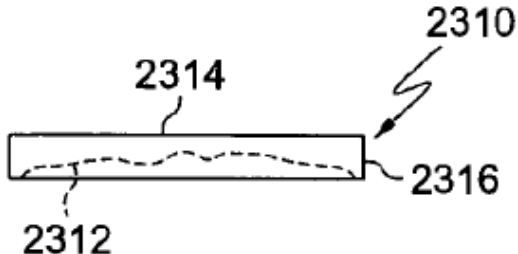
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p>  <p data-bbox="947 695 1108 737">FIG. 24A</p> <ul data-bbox="596 802 789 834" style="list-style-type: none">• Figure 24B

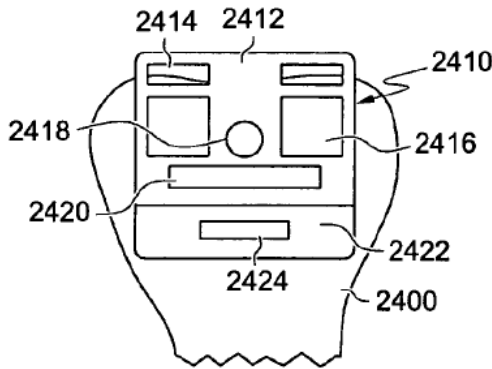
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p> <div data-bbox="760 337 1234 727"> </div> <p data-bbox="940 743 1094 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 846 730 878">• [0294] <li data-bbox="695 919 1860 1203">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface. <li data-bbox="598 1252 730 1284">• [0069]

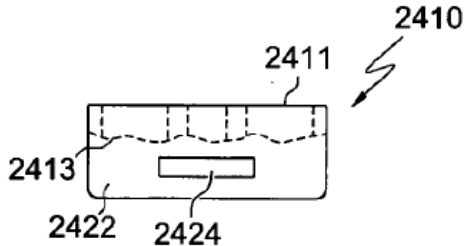
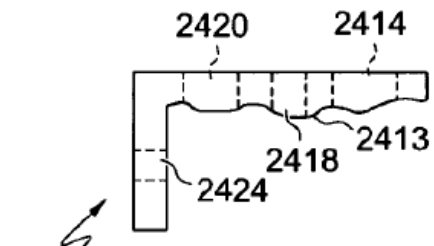
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ FIGS. 25A-Q illustrate tibial cutting blocks and molds used to create a surface perpendicular to the anatomic axis for receiving the tibial portion of a knee implant. • [0295] <ul style="list-style-type: none"> ○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. • [0296] <ul style="list-style-type: none"> ○ The reusable exterior piece has a superior surface 2322 and an inferior surface 2324 that mates with the first piece 2310. The reusable exterior piece 2320 includes cutting guides 2328, to assist the surgeon in performing the tibial surface cut described above. As shown herein a plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the tibial cut. • [0300] <ul style="list-style-type: none"> ○ A guide plate 2326 is provided that extends along the side of at least a portion of the exterior piece 2320. The guide plate 2326 provides one or more slots or guides 2328 through which a saw blade can be inserted to achieve the cut desired of the tibial surface. Additionally, the slot, or guide, can be configured so that the saw blade cuts at a line perpendicular to the mechanical axis, or so that it cuts at a line that is

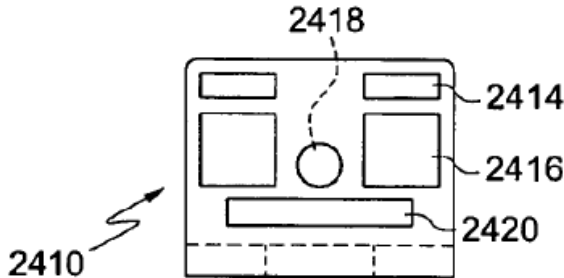
Claims of US 8,623,026	Invalidity Contentions
	<p>perpendicular to the mechanical axis, but has a 4-7° slope in the sagittal plane to match the normal slope of the tibia.</p> <ul style="list-style-type: none"> • Figures 25A & 25B <ul style="list-style-type: none"> ○  ○  <p>FIG. 25B</p> • [0301] <ul style="list-style-type: none"> ○ Optionally, a central bore 2330 can be provided that, for example, enables a drill to ream a hole into the bone for the stem of the tibial component of the knee implant. • Figure 25C

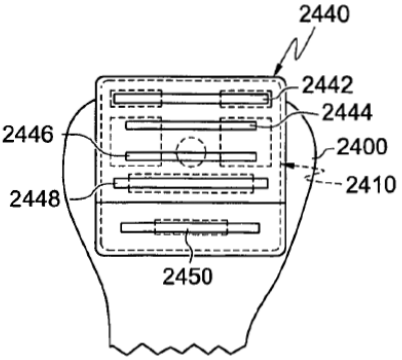
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 709 297">○</p> <div data-bbox="772 347 1161 594"> </div> <p data-bbox="842 618 1031 667">FIG. 25C</p> <ul style="list-style-type: none"> <li data-bbox="598 748 1858 927"> <p>• [0297]</p> <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. <li data-bbox="598 967 1858 1187"> <p>• [0298]</p> <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci. <li data-bbox="598 1227 789 1260"> <p>• Figure 25E</p>

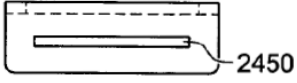
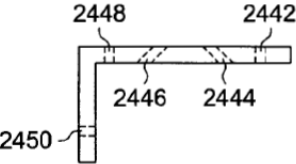
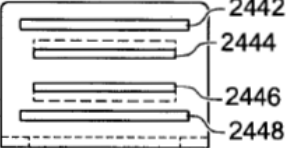
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 341 1270 592">  </div> <p data-bbox="840 633 1102 698">FIG. 25E</p> <ul style="list-style-type: none"> <li data-bbox="598 763 735 803">• [0070] <ul style="list-style-type: none"> <li data-bbox="693 836 1795 909">○ FIGS. 26A-O illustrate femur cutting blocks and molds used to create a surface for receiving the femoral portion of a knee implant. <li data-bbox="598 950 735 990">• [0312] <ul style="list-style-type: none"> <li data-bbox="693 1023 1816 1128">○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. <li data-bbox="598 1169 735 1209">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 1242 1837 1347">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures

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	<p>2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> Fig. 26A <ul style="list-style-type: none">  [0314]-[0315]

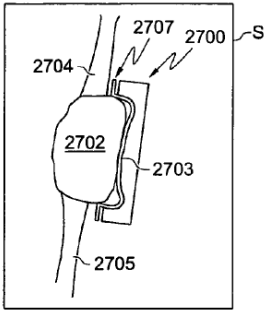
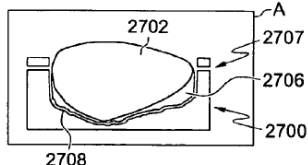
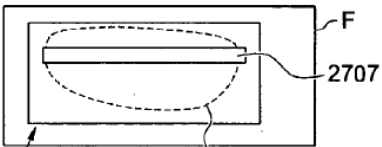
Claims of US 8,623,026	Invalidity Contentions
	<p>○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur.</p> <p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>FIG. 26B</p> </div> <div style="text-align: center;">  <p>FIG. 26C</p> </div> </div> <ul style="list-style-type: none"> • [0316]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ FIG. 26D illustrates a top view of the first portion 2410. The bottom of the illustration corresponds to an anterior location relative to the knee joint. From the top view, each of the apertures is illustrated as described above. As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention. • Figure 26D <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26D</p> <ul style="list-style-type: none"> • [0317]-[0318] <ul style="list-style-type: none"> ○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example,

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	<p>at a 45° angle. Other angles are also possible without departing from the scope of the invention.</p> <p>As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer.</p> <ul style="list-style-type: none"> • Figure 26E <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26E</p> <ul style="list-style-type: none"> • [0319] <ul style="list-style-type: none"> ○ FIG. 26F illustrates a side view of the second, exterior, cutting block portion 2440. From the side view a single aperture 2450 is provided to access the femur cut. FIG. 26G is another side view of the second, exterior, portion 2440 showing the location and relative angles of the rectangular grooves. As evidenced from this view, the orientation of the grooves 2442, 2448 and 2450 is perpendicular to at least one surface of the second, exterior, portion 2440. The orientation of the grooves 2444, 2446 is at an angle

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	<p>that is not perpendicular to at least one surface of the second, exterior portion 2440. These grooves (2444, 2446) facilitate making the angled chamfer cuts to the femur. FIG. 26H is a top view of the second, exterior portion 2440. As will be appreciated by those of skill in the art, the location and orientation of the grooves will change depending upon the design of the femoral implant and the shape required of the femur to communicate with the implant.</p> <ul style="list-style-type: none"> • Figures 26F & 26G <ul style="list-style-type: none"> ○ <div style="text-align: center;">    </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> FIG. 26F FIG. 26G FIG. 26H </div> <ul style="list-style-type: none"> • [0253] <ul style="list-style-type: none"> ○ Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee. • [0042] <ul style="list-style-type: none"> ○ The invention is also directed to tools. A is disclosed that tool comprises: a mold having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block. Another tool is disclosed that is formed at least

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	<p>partially in situ and comprises: a mold formed in situ using at least one of an inflatable hollow device or a retaining device to conform to the joint surface on at least one surface having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block.</p> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C

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	<p>○</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;">    </div> <p style="text-align: center;">FIG. 27A FIG. 27B FIG. 27C</p> <ul style="list-style-type: none"> • Claim 48 <ul style="list-style-type: none"> ○ A tool formed at least partially in situ comprising: <ul style="list-style-type: none"> a mold formed in situ using at least one of an inflatable hollow device or a retaining device to conform to the joint surface on at least one surface having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block. • Abstract <ul style="list-style-type: none"> ○ Disclosed herein are methods, compositions and tools for repairing articular surfaces repair materials and for repairing an articular surface. The articular surface repairs are customizable or highly selectable by patient and geared toward providing optimal fit and function. The surgical tools are designed to be customizable or highly selectable by patient to increase the speed, accuracy and simplicity of performing total or partial arthroplasty.

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	<ul style="list-style-type: none"> • [0002] <ul style="list-style-type: none"> ○ The present invention relates to orthopedic methods, systems and prosthetic devices and more particularly relates to methods, systems and devices for articular resurfacing. The present invention also includes surgical molds designed to achieve optimal cut planes in a joint in preparation for installation of a joint implant. • [0037] <ul style="list-style-type: none"> ○ In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool comprising one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). In certain embodiments, the tool comprises Lucite silastic and/or other polymers or suitable materials. The tool can be re-useable or single-use. The tool can be comprised of a single component or multiple components. In certain embodiments, the tool comprises an array of adjustable, closely spaced pins. In any embodiments described herein, the surgical tool can be designed to further comprise an aperture therein, for example one or more apertures having dimensions (e.g., diameter, depth, etc.) smaller or equal to one or more dimensions of the implant and/or one or more apertures adapted to receive one or more injectables. Any of the tools described herein can further include one or more curable (hardening) materials or compositions, for example that are injected through one or more apertures in the tool and which solidify to form an impression of the articular surface. • [0266] <ul style="list-style-type: none"> ○ Mechanical devices can be used for surgical assistance (e.g., surgical tools), for example using gels, molds, plastics or metal. One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define

Claims of US 8,623,026	Invalidity Contentions
	<p>the articular and/or bone surface and shape. These objects' coordinates can be utilized to either shape the device, e.g. using a CAD/CAM technique, to be adapted to a patient's articular anatomy or, alternatively, to select a typically pre-made device that has a good fit with a patient's articular anatomy. The device can have a surface and shape that will match all or portions of the articular or bone surface and shape, e.g. similar to a "mirror image." The device can include apertures, slots and/or holes to accommodate surgical instruments such as drills, reamers, curettes, k-wires, screws and saws.</p> <ul style="list-style-type: none"> • [0267] <ul style="list-style-type: none"> ○ Typically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general instrument orientation for subsequent placement of an articular repair system or for facilitating placement of the articular repair system. Moreover, the device can be designed so that the depth of the drill, reamer or other surgical instrument can be controlled, e.g., the drill cannot go any deeper into the tissue than defined by the device, and the size of the hole in the block can be designed to essentially match the size of the implant. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. Alternatively, the openings in the device can be made larger than needed to accommodate these instruments. The device can also be configured to conform to the articular shape. The apertures, or openings, provided can be wide enough to allow for varying the position or angle of the surgical instrument, e.g., reamers, saws, drills, curettes and other surgical instruments. An instrument guide, typically comprised of a relatively hard material, can then be applied to the device. The device helps orient the instrument guide relative to the three-dimensional anatomy of the joint. • [0274]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ One or more molds can be used during the surgery. For example, in the hip, a mold can be initially applied to the proximal femur that closely approximates the 3D anatomy prior to the resection of the femoral head. The mold can include an opening to accommodate a saw (see FIGS. 28-29). The opening is positioned to achieve an optimally placed surgical cut for subsequent reaming and placement of the prosthesis. A second mold can then be applied to the proximal femur after the surgical cut has been made. The second mold can be useful for guiding the direction of a reamer prior to placement of the prosthesis. As can be seen in this, as well as in other examples, molds can be made for joints prior to any surgical intervention. However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures. • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints

Claims of US 8,623,026	Invalidity Contentions
	<p>or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0277] <ul style="list-style-type: none"> ○ In another embodiment, a frame can be applied to the bone or the cartilage in areas other than the diseased bone or cartilage. The frame can include holders and guides for surgical instruments. The frame can be attached to one or preferably more previously defined anatomic reference points. Alternatively, the position of the frame can be cross-registered relative to one, or more, anatomic landmarks, using an imaging test or intraoperative measurement, for example one or more fluoroscopic images acquired intraoperatively. One or more electronic images or intraoperative measurements including using mechanical devices can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to move one or more of the holders or guides for surgical instruments. Typically, a position will be chosen that will result in a surgically or anatomically desirable cut plane or drill hole orientation for subsequent placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for

Claims of US 8,623,026	Invalidity Contentions
	<p>placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties.</p> <ul style="list-style-type: none"> • [0287] <ul style="list-style-type: none"> ○ The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical tool can include one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface facing the surgical tool and, accordingly, will form a mirror image impression of the surface upon hardening, thereby recreating a normal or near normal articular surface. In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint. • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is

Claims of US 8,623,026	Invalidity Contentions
	<p>then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141.</p> <ul style="list-style-type: none">• Figure 23

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] -- Optional 2101 --> 2100 2100 --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 -- Optional 2121 --> 2120 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 -- Optional 2131 --> 2130 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 -- Optional 2133 --> 2132 2134 -- Optional 2135 --> 2134 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 -- Optional 2141 --> 2140 2140 --> 2142((Perform Implantation 2142)) 2102 --> 2100 </pre> <ul style="list-style-type: none"> • [0291]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times. • [0292]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Thus, surgical tools described herein can also be designed and used to control drill alignment, depth and width, for example when preparing a site to receive an implant. For example, the tools described herein, which typically conform to the joint surface, can provide for improved drill alignment and more accurate placement of any implant. <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] ("The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein."); [0253] ("Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee."); [0274] ("However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures."); [0289] ("Other more sophisticated scanning procedures can be used to derive this information without departing from the</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>
<p>[15.B.i] at least one surface for engaging a first articular surface of a joint,</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious at least one surface for engaging a first articular surface of a joint, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0037] <ul style="list-style-type: none"> ○ In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool comprising one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). In certain embodiments, the tool comprises Lucite silastic and/or other polymers or suitable materials. The tool can be re-useable or single-use. The tool can be comprised of a single component or multiple components. In certain embodiments, the tool comprises an array of adjustable, closely

Claims of US 8,623,026	Invalidity Contentions
	<p>spaced pins. In any embodiments described herein, the surgical tool can be designed to further comprise an aperture therein, for example one or more apertures having dimensions (e.g., diameter, depth, etc.) smaller or equal to one or more dimensions of the implant and/or one or more apertures adapted to receive one or more injectables. Any of the tools described herein can further include one or more curable (hardening) materials or compositions, for example that are injected through one or more apertures in the tool and which solidify to form an impression of the articular surface.</p> <ul style="list-style-type: none"> • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • [0277]

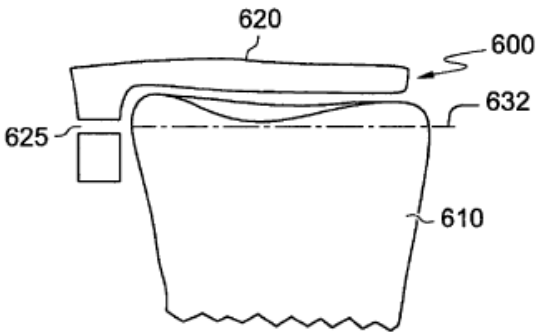
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In another embodiment, a frame can be applied to the bone or the cartilage in areas other than the diseased bone or cartilage. The frame can include holders and guides for surgical instruments. The frame can be attached to one or preferably more previously defined anatomic reference points. Alternatively, the position of the frame can be cross-registered relative to one, or more, anatomic landmarks, using an imaging test or intraoperative measurement, for example one or more fluoroscopic images acquired intraoperatively. One or more electronic images or intraoperative measurements including using mechanical devices can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to move one or more of the holders or guides for surgical instruments. Typically, a position will be chosen that will result in a surgically or anatomically desirable cut plane or drill hole orientation for subsequent placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or

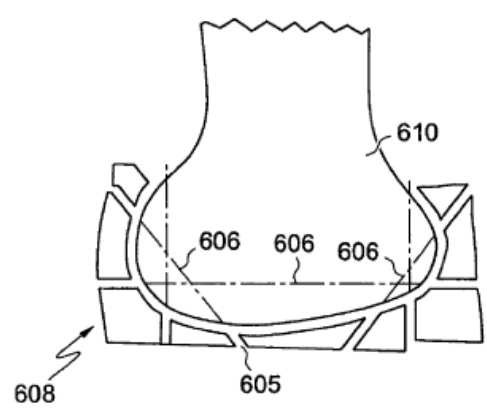
Claims of US 8,623,026	Invalidity Contentions
	<p>biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties.</p> <ul style="list-style-type: none"> • [0287] <ul style="list-style-type: none"> ○ The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical tool can include one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface facing the surgical tool and, accordingly, will form a mirror image impression of the surface upon hardening, thereby recreating a normal or near normal articular surface. In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint. • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141.

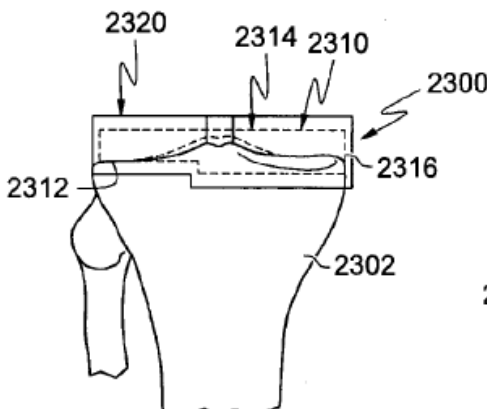
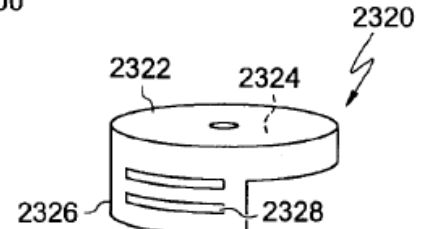
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> Figure 23 <ul style="list-style-type: none"> <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 --> 2142((Perform Implantation 2142)) 2100 -.-> 2102 2130 </pre>

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0291] <ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none">• [0068]<ul style="list-style-type: none">○ FIG. 24A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. 24B depicts, in crosssection, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone.• [0293]<ul style="list-style-type: none">○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone.• Figure 24A

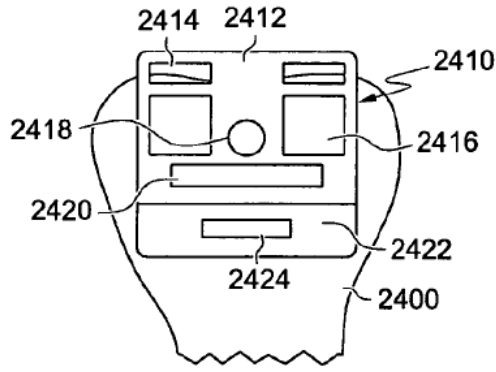
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p>  <p data-bbox="945 690 1113 738">FIG. 24A</p> <ul style="list-style-type: none"><li data-bbox="598 795 787 836">• Figure 24B

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730">  </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 844 735 876">• [0294] <li data-bbox="693 917 1858 1209">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.. <li data-bbox="598 1250 735 1282">• [0295]

Claims of US 8,623,026	Invalidity Contentions
	<p>○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone.</p> <p>• Figures 25A & 25B</p> <p>○</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p style="text-align: center;">FIG. 25A</p> <p style="text-align: center;">FIG. 25B</p> <p>• [0297]</p>

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci. • Figure 25E <ul style="list-style-type: none"> ○ <div data-bbox="753 816 1268 1075" data-label="Image"> </div> • [0312]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. • [0313] ○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention. • Fig. 26A

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p>  <p>FIG. 26A</p> <ul style="list-style-type: none"> • [0314]-[0315] <ul style="list-style-type: none"> ○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur. <p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="751 370 1213 617"> </div> <p>FIG. 26B</p> <div data-bbox="1239 370 1675 678"> </div> <p>FIG. 26C</p> <ul style="list-style-type: none"> • [0317]-[0318] <ul style="list-style-type: none"> ○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example, at a 45° angle. Other angles are also possible without departing from the scope of the invention. <p>As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer.</p>

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C

Claims of US 8,623,026	Invalidity Contentions
	<div data-bbox="688 272 1751 662"> <p>FIG. 27A</p> <p>FIG. 27B</p> <p>FIG. 27C</p> </div> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] ("The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.");</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>[0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>
<p>[15.B.ii] the at least one surface being substantially a negative of portions or all of the first articular surface;</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious the at least one surface being substantially a negative of portions or all of the first articular surface, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0037]

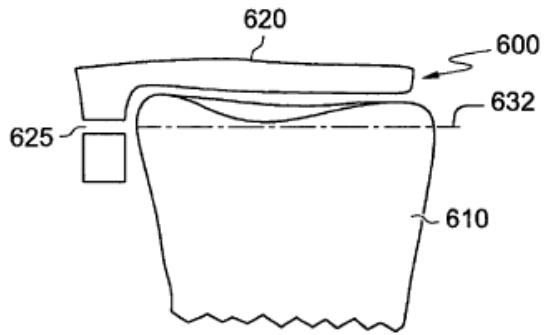
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool comprising one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). In certain embodiments, the tool comprises Lucite silastic and/or other polymers or suitable materials. The tool can be re-useable or single-use. The tool can be comprised of a single component or multiple components. In certain embodiments, the tool comprises an array of adjustable, closely spaced pins. In any embodiments described herein, the surgical tool can be designed to further comprise an aperture therein, for example one or more apertures having dimensions (e.g., diameter, depth, etc.) smaller or equal to one or more dimensions of the implant and/or one or more apertures adapted to receive one or more injectables. Any of the tools described herein can further include one or more curable (hardening) materials or compositions, for example that are injected through one or more apertures in the tool and which solidify to form an impression of the articular surface. • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for

Claims of US 8,623,026	Invalidity Contentions
	<p>facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0287] <ul style="list-style-type: none"> ○ The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical tool can include one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface facing the surgical tool and, accordingly, will form a mirror image impression of the surface upon hardening, thereby recreating a normal or near normal articular surface. In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none">• [0288]<ul style="list-style-type: none">○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141.• Figure 23

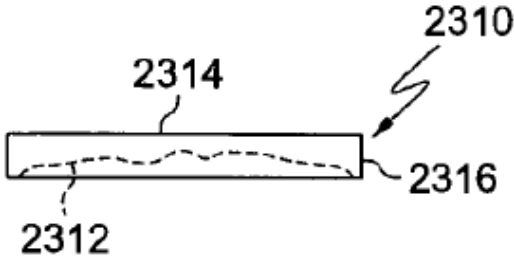
Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <pre>graph TD; 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] --> 2101((Optional 2101)); 2100 --> 2102[Measure Thickness of Adjacent Cartilage 2120]; 2102 --> 2121((Optional 2121)); 2102 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130]; 2130 --> 2131((Optional 2131)); 2130 --> 2132[Select Best Fitting Mold in Library 2132]; 2130 --> 2134[Generate Custom Patient Specific Mold 2134]; 2132 --> 2133((Optional 2133)); 2134 --> 2135((Optional 2135)); 2132 --> 2140[Prepare Implantation Site 2140]; 2134 --> 2140; 2140 --> 2141((Optional 2141)); 2140 --> 2142((Perform Implantation 2142));</pre> <p>• [0291]</p>

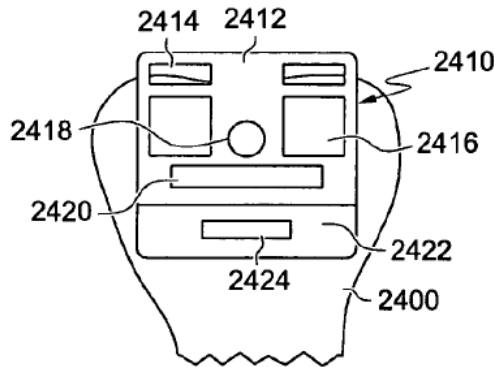
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times. • [0293]

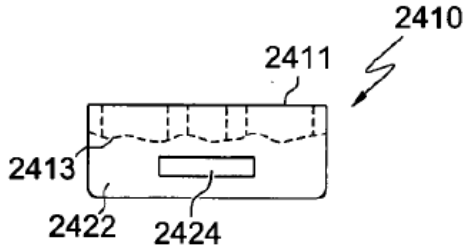
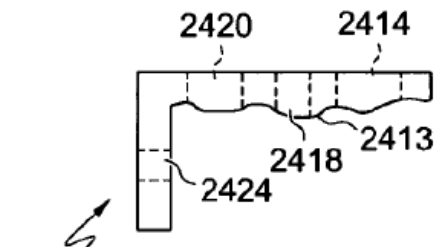
Claims of US 8,623,026	Invalidity Contentions
	<p>○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone.</p> <ul style="list-style-type: none"> • Figure 24A <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 24A</p> <ul style="list-style-type: none"> • Figure 24B

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p> <div data-bbox="760 337 1234 727"> </div> <p data-bbox="940 743 1094 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="596 846 730 878">• [0295] <ul style="list-style-type: none"> <li data-bbox="695 919 1850 1243">○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. <li data-bbox="596 1284 898 1317">• Figures 25A & 25B

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="751 310 1631 774" data-label="Image"> <p>FIG. 25A</p> <p>FIG. 25B</p> </div> <ul style="list-style-type: none"> • [0297] <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci. • Figure 25E

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p>  <p>FIG. 25E</p> <ul style="list-style-type: none"> • [0312] <ul style="list-style-type: none"> ○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. • [0313] <ul style="list-style-type: none"> ○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is

Claims of US 8,623,026	Invalidity Contentions
	<p>manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> • Fig. 26A <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26A</p> <ul style="list-style-type: none"> • [0314]-[0315] <ul style="list-style-type: none"> ○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the

Claims of US 8,623,026	Invalidity Contentions
	<p>interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur.</p> <p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end; margin-top: 20px;"> <div style="text-align: center;">  <p>FIG. 26B</p> </div> <div style="text-align: center;">  <p>FIG. 26C</p> </div> </div> <ul style="list-style-type: none"> • [0317]-[0318] <ul style="list-style-type: none"> ○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular

Claims of US 8,623,026	Invalidity Contentions
	<p>grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example, at a 45° angle. Other angles are also possible without departing from the scope of the invention.</p> <p>As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer.</p> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A. The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C

Claims of US 8,623,026	Invalidity Contentions
	<div data-bbox="688 310 1751 698" data-label="Image"> <p>FIG. 27A is a side cross-sectional view of a medical device 2700. It features a central component 2702, a surrounding sleeve 2703, and a distal tip 2704. A lead wire 2705 is attached to the proximal end. A dashed line 2707 indicates an internal feature. FIG. 27B is a top-down view of the device 2700, showing the oval-shaped component 2702 and the surrounding sleeve 2706. A dashed line 2707 is also shown. FIG. 27C is a side cross-sectional view of the device 2700, showing the component 2702 and the sleeve 2707. A dashed line 2700 is shown.</p> </div> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] ("The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown,</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>
<p>[15.B.iii] at least a portion of the at least one surface further including an anatomical relief; and</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious at least a portion of the at least one surface further including an anatomical relief, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0037]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool comprising one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • [0277] <ul style="list-style-type: none"> ○ In another embodiment, a frame can be applied to the bone or the cartilage in areas other than the diseased bone or cartilage. The frame can include holders and guides for surgical instruments. The frame can be attached to one or preferably more previously defined anatomic reference points. Alternatively, the position of the frame can be

Claims of US 8,623,026	Invalidity Contentions
	<p>cross-registered relative to one, or more, anatomic landmarks, using an imaging test or intraoperative measurement, for example one or more fluoroscopic images acquired intraoperatively. One or more electronic images or intraoperative measurements including using mechanical devices can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to move one or more of the holders or guides for surgical instruments. Typically, a position will be chosen that will result in a surgically or anatomically desirable cut plane or drill hole orientation for subsequent placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0287]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical tool can include one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface facing the surgical tool and, accordingly, will form a mirror image impression of the surface upon hardening, thereby recreating a normal or near normal articular surface. In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint. • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141. • Figure 23

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] -- Optional 2101 --> 2100 2100 --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 -- Optional 2121 --> 2120 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 -- Optional 2131 --> 2130 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 -- Optional 2133 --> 2132 2134 -- Optional 2135 --> 2134 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 -- Optional 2141 --> 2140 2140 --> 2142((Perform Implantation 2142)) 2102 --> 2100 </pre> <ul style="list-style-type: none"> • [0166]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In another embodiment, a balloon such as that shown in FIGS. 11A-E, can be used as the implantation device. Different balloon shapes and sizes can be made available. A detailed description of all possible shapes and sizes for the balloons is not included to avoid obscuring the invention, but would be apparent to those of skill in the art. Where a balloon is used, it can be inserted into a joint and inflated. The size, height, shape and position of the balloon can be evaluated arthroscopically or via an open incision or using, for example, an imaging test relative to the articular surface and the other articular strictures. Range of motion testing can be performed in order to ensure adequate size, shape and position of the device during the full range of motion. • [0167] ○ After insertion, the balloon can be slowly injected with, for example, a self-hardening material, or material that hardens upon activation. Suitable materials are described below and would be apparent to those of skill in the art. Typically, upon injection, the material is in a fluid or semi-fluid state. The material expands the balloon as it is injected which results in the balloon taking on the shape of the articular surface, for example as shown in FIG. 11A, and other articular structures such that it fills the defect. • Figures 11A and 11B

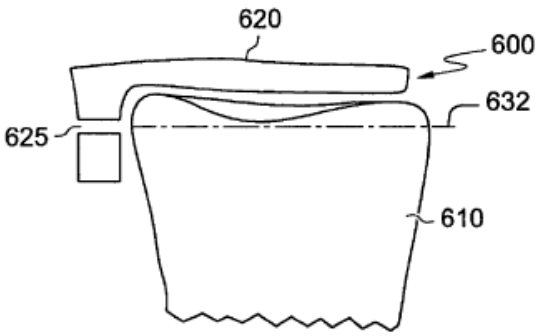
Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="751 316 1617 771"> <p>FIG. 11A FIG. 11B</p> </div> <ul style="list-style-type: none"> • [0178] <ul style="list-style-type: none"> ○ Differences in wall thickness, pressure tolerances and expandability of balloons can also be used to influence the resulting shape of the injected material. • [0179] <ul style="list-style-type: none"> ○ The results of using inflation devices, or balloons, with differing wall thicknesses or pressure tolerances is shown in FIGS. 12A-F. As shown in FIG. 12A the balloon 1200 has an upper surface 1210 and a lower surface 1212 along with a proximal end 1214 and a distal end 1216. The relative pressure tolerance of the balloon or inflation device 1200 is lower on the lower surface 1212 than the upper surface 1210. As a result, the upper surface of the balloon 1210 has a relatively flat configuration relative to its corresponding joint surface while the lower surface 1212 has a relatively conforming shape relative to its corresponding joint surface.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0180] <ul style="list-style-type: none"> ○ Turning now to FIG. 12B, the inflation device used 1220 has a relatively constant pressure tolerance that is relatively high which results in both the upper surface 1210 and the lower surface 1212 having relatively flat configurations relative to each of its corresponding joint surfaces, regardless of the joint surface anatomy. • [0181] <ul style="list-style-type: none"> ○ FIG. 12C illustrates a balloon 1230 having a low inflation pressure at its proximal 1214 and distal 1216 ends, with a higher inflation pressure at a central region 1218. The result of this configuration is that when the balloon is inflated, the proximal and distal ends inflate to a greater profile (e.g., height) than the central region. The inflation pressure of the central region, although higher than the proximal and distal ends, can be set such that the central region has a relatively flat configuration relative to the corresponding joint surfaces, as shown, or can be configured to achieve the result shown in FIG. 12A. • [0056] <ul style="list-style-type: none"> ○ FIGS. 12A-E illustrate a variety of cross-sectional shapes achieved using balloons with variable wall thicknesses or material compositions. In FIG. 12A the inflation device enables the implant to achieve a surface conforming to the irregularities of the joint surface. In FIG. 12B the inflation device enables the implant to achieve a surface that sits above the irregular joint surface; FIG. 12C illustrates a device formed where a central portion of the device sits above the joint surface irregularities while the proximal and distal ends illustrated form a lateral abutting surface to the joint defects. FIG. 12D illustrates a device formed using a first inflation device within a second inflation device, with an exterior configuration similar to that shown in FIG. 12A;

Claims of US 8,623,026	Invalidity Contentions
	<p>while FIG. 12E illustrates an alternative device formed using at least two different inflation devices having an exterior shape similar to the device shown in FIG. 12C.</p> <ul style="list-style-type: none"> • Figures 12A-E <ul style="list-style-type: none"> ○ <div style="text-align: center;"> <p>FIG. 12A FIG. 12B FIG. 12C</p> <p>FIG. 12D FIG. 12E</p> </div> <ul style="list-style-type: none"> • [0182] <ul style="list-style-type: none"> ○ As will be appreciated by those of skill in the art, any of these balloons can be configured to have varying properties resulting in portions of the wall being less rigid than other portions, within the same balloon, e.g. a rigid wall with high inflation

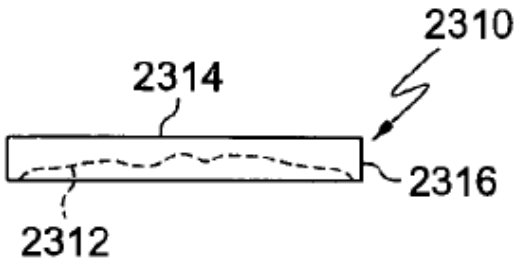
Claims of US 8,623,026	Invalidity Contentions
	<p>pressures in the periphery and a less rigid wall with intermediate or low inflation pressures in the center. Where there is more than one thickness to the balloon, it could, for example, have less stiffness anteriorly; greater stiffness centrally, and less stiffness posteriorly. The wall thickness variability will enable the device to accommodate shape formation. Central thickness will help prevent the device from fully conforming to the irregular surface of the joint, which may be important where there are irregularities to the joint surface, such as bone spurs. Alternatively, if the central portion is of less stiffness than the anterior and posterior sections, the device would be configured to conform more closely to the shape of the joint surface, including any irregularities. The closer the device conforms to the joint shape, the more the device seats within the joint.</p> <ul style="list-style-type: none"> • [0291] <ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a

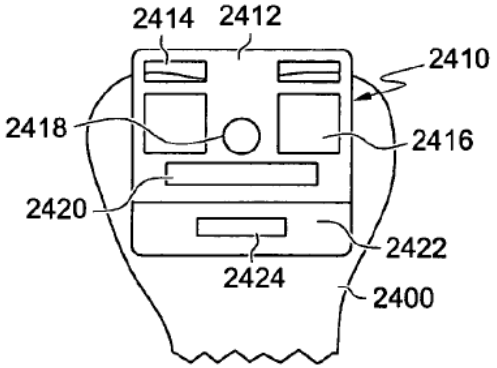
Claims of US 8,623,026	Invalidity Contentions
	<p>more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.</p> <ul style="list-style-type: none"> • [0292] <ul style="list-style-type: none"> ○ Thus, surgical tools described herein can also be designed and used to control drill alignment, depth and width, for example when preparing a site to receive an implant. For example, the tools described herein, which typically conform to the joint surface, can provide for improved drill alignment and more accurate placement of any implant. • Figure 24A

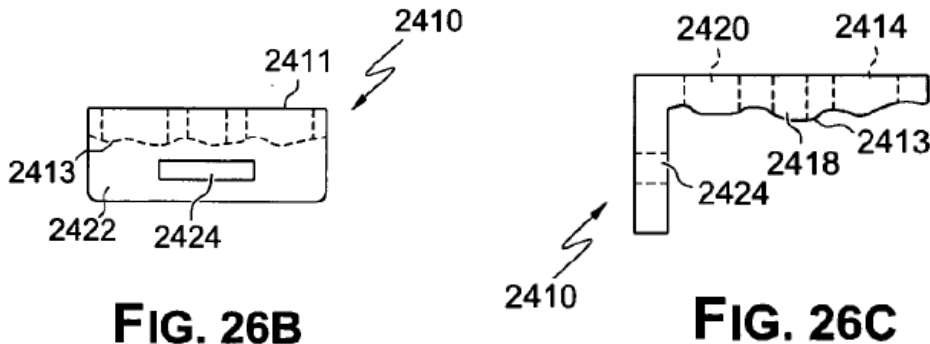
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p>  <p data-bbox="945 690 1113 738">FIG. 24A</p> <ul style="list-style-type: none"><li data-bbox="598 795 787 836">• Figure 24B

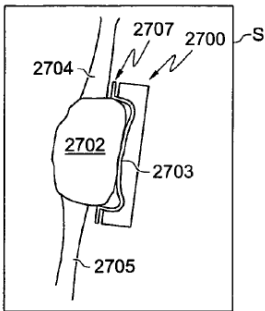
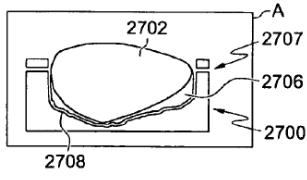
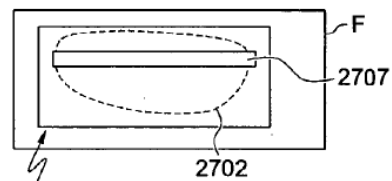
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="762 334 1230 724"> </div> <p data-bbox="940 743 1094 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 844 730 876">• [0295] <ul style="list-style-type: none"> <li data-bbox="693 917 1843 1133">○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. <li data-bbox="598 1177 898 1209">• Figures 25A & 25B

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="751 310 1631 774" data-label="Image"> <p>FIG. 25A</p> <p>FIG. 25B</p> </div> <ul style="list-style-type: none"> • [0297] <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci. • Figure 25E

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p>  <p>FIG. 25E</p> <ul style="list-style-type: none"> • [0313] <ul style="list-style-type: none"> ○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • Fig. 26A <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26A</p> <ul style="list-style-type: none"> • [0314]-[0315] <ul style="list-style-type: none"> ○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur. <p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p>

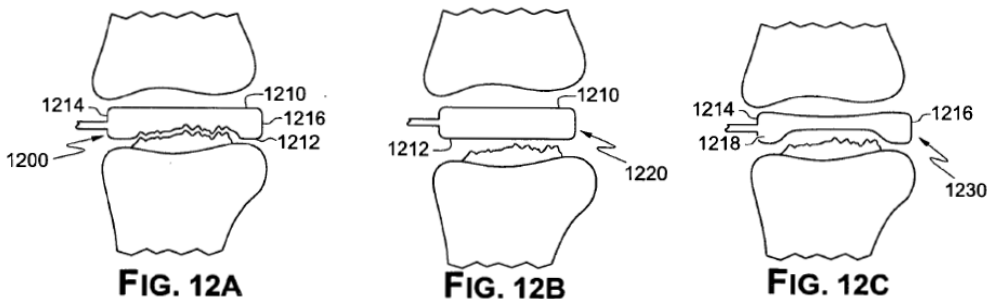
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="text-align: center; margin: 20px 0;">  <p>FIG. 26B is a cross-sectional view of a rectangular block with a dashed line indicating a cut. Labels 2411, 2413, 2422, and 2424 point to various features. A lightning bolt symbol labeled 2410 points to the top right corner. FIG. 26C is a cross-sectional view of a block with a wavy top surface. Labels 2420, 2414, 2418, 2413, and 2424 point to various features. A lightning bolt symbol labeled 2410 points to the bottom left corner.</p> </div> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326]

Claims of US 8,623,026	Invalidity Contentions
	<p>○ FIG. 27B is a view in the axial plane A The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702.</p> <p>• Figures 27A, 27B & 27C</p> <p>○</p> <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  <p>FIG. 27A</p> </div> <div style="text-align: center;">  <p>FIG. 27B</p> </div> <div style="text-align: center;">  <p>FIG. 27C</p> </div> </div> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>For example, Berez teaches that “the following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.” Berez at [0074]. Thus, it would be obvious to a POSITA that features described throughout the specification can be applied to other embodiments. In fact, Berez specifically teaches the disclosed balloon technique can be applied to the disclosed molds/tool guides/templates. Berez at [0278] (“Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools.”). Thus, it would be obvious to a POSITA to apply the methods of anatomical relief used with the balloon technique to the disclosed molds/tool guides/templates, at least under Conformis’s implicit construction. See the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0166] <ul style="list-style-type: none"> ○ In another embodiment, a balloon such as that shown in FIGS. 11A-E, can be used as the implantation device. Different balloon shapes and sizes can be made available. A detailed description of all possible shapes and sizes for the balloons is not included to avoid obscuring the invention, but would be apparent to those of skill in the art. Where a balloon is used, it can be inserted into a joint and inflated. The size, height, shape and position of the balloon can be evaluated arthroscopically or via an open incision or using, for example, an imaging test relative to the articular surface and the other articular strictures. Range of motion testing can be performed in order to ensure adequate size, shape and position of the device during the full range of motion.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0167] <ul style="list-style-type: none"> ○ After insertion, the balloon can be slowly injected with, for example, a self-hardening material, or material that hardens upon activation. Suitable materials are described below and would be apparent to those of skill in the art. Typically, upon injection, the material is in a fluid or semi-fluid state. The material expands the balloon as it is injected which results in the balloon taking on the shape of the articular surface, for example as shown in FIG. 11A, and other articular structures such that it fills the defect. • [0178] <ul style="list-style-type: none"> ○ Differences in wall thickness, pressure tolerances and expandability of balloons can also be used to influence the resulting shape of the injected material. • [0179] <ul style="list-style-type: none"> ○ The results of using inflation devices, or balloons, with differing wall thicknesses or pressure tolerances is shown in FIGS. 12A-F. As shown in FIG. 12A the balloon 1200 has an upper surface 1210 and a lower surface 1212 along with a proximal end 1214 and a distal end 1216. The relative pressure tolerance of the balloon or inflation device 1200 is lower on the lower surface 1212 than the upper surface 1210. As a result, the upper surface of the balloon 1210 has a relatively flat configuration relative to its corresponding joint surface while the lower surface 1212 has a relatively conforming shape relative to its corresponding joint surface. • [0180]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Turning now to FIG. 12B, the inflation device used 1220 has a relatively constant pressure tolerance that is relatively high which results in both the upper surface 1210 and the lower surface 1212 having relatively flat configurations relative to each of its corresponding joint surfaces, regardless of the joint surface anatomy. • [0181] <ul style="list-style-type: none"> ○ FIG. 12C illustrates a balloon 1230 having a low inflation pressure at its proximal 1214 and distal 1216 ends, with a higher inflation pressure at a central region 1218. The result of this configuration is that when the balloon is inflated, the proximal and distal ends inflate to a greater profile (e.g., height) than the central region. The inflation pressure of the central region, although higher than the proximal and distal ends, can be set such that the central region has a relatively flat configuration relative to the corresponding joint surfaces, as shown, or can be configured to achieve the result shown in FIG. 12A. • [0056] <ul style="list-style-type: none"> ○ FIGS. 12A-E illustrate a variety of cross-sectional shapes achieved using balloons with variable wall thicknesses or material compositions. In FIG. 12A the inflation device enables the implant to achieve a surface conforming to the irregularities of the joint surface. In FIG. 12B the inflation device enables the implant to achieve a surface that sits above the irregular joint surface; FIG. 12C illustrates a device formed where a central portion of the device sits above the joint surface irregularities while the proximal and distal ends illustrated form a lateral abutting surface to the joint defects. FIG. 12D illustrates a device formed using a first inflation device within a second inflation device, with an exterior configuration similar to that shown in FIG. 12A; while FIG. 12E illustrates an alternative device formed using at least two different inflation devices having an exterior shape similar to the device shown in FIG. 12C.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • Figures 12A, 12B, and 12C <ul style="list-style-type: none"> ○  • [0182] <ul style="list-style-type: none"> ○ As will be appreciated by those of skill in the art, any of these balloons can be configured to have varying properties resulting in portions of the wall being less rigid than other portions, within the same balloon, e.g. a rigid wall with high inflation pressures in the periphery and a less rigid wall with intermediate or low inflation pressures in the center. Where there is more than one thickness to the balloon, it could, for example, have less stiffness anteriorly; greater stiffness centrally, and less stiffness posteriorly. The wall thickness variability will enable the device to accommodate shape formation. Central thickness will help prevent the device from fully conforming to the irregular surface of the joint, which may be important where there are irregularities to the joint surface, such as bone spurs. Alternatively, if the central portion is of less stiffness than the anterior and posterior sections, the device would be configured to conform more closely to the shape of the joint surface, including any irregularities. The closer the device conforms to the joint shape, the more the device seats within the joint.

Claims of US 8,623,026	Invalidity Contentions
	<p>Additionally, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] (“The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>

Claims of US 8,623,026	Invalidity Contentions
<p>[15.C.i] at least one guide for directing movement of a surgical instrument; and</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious at least one guide for directing movement of a surgical instrument, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0266] <ul style="list-style-type: none"> ○ Mechanical devices can be used for surgical assistance (e.g., surgical tools), for example using gels, molds, plastics or metal. One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be utilized to either shape the device, e.g. using a CAD/CAM technique, to be adapted to a patient's articular anatomy or, alternatively, to select a typically pre-made device that has a good fit with a patient's articular anatomy. The device can have a surface and shape that will match all or portions of the articular or bone surface and shape, e.g. similar to a "mirror image." The device can include apertures, slots and/or holes to accommodate surgical instruments such as drills, reamers, curettes, k-wires, screws and saws. • [0267] <ul style="list-style-type: none"> ○ Typically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general instrument orientation for subsequent placement of an articular repair system or for facilitating placement of the articular repair system. Moreover, the device can be designed so that the depth of the drill, reamer or other surgical instrument can be controlled, e.g., the drill cannot go any deeper into the tissue than defined by the device, and the size of the hole in the block can be designed to essentially match the size of the implant. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the

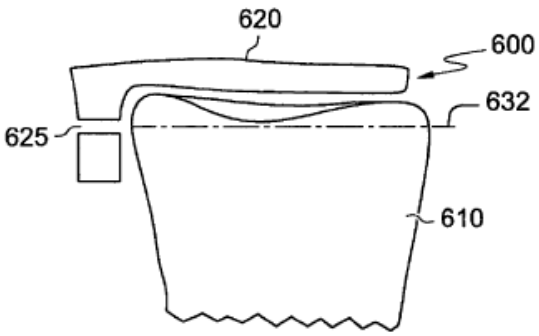
Claims of US 8,623,026	Invalidity Contentions
	<p>position of these slots or holes. Alternatively, the openings in the device can be made larger than needed to accommodate these instruments. The device can also be configured to conform to the articular shape. The apertures, or openings, provided can be wide enough to allow for varying the position or angle of the surgical instrument, e.g., reamers, saws, drills, curettes and other surgical instruments. An instrument guide, typically comprised of a relatively hard material, can then be applied to the device. The device helps orient the instrument guide relative to the three-dimensional anatomy of the joint.</p> <ul style="list-style-type: none"> • [0274] <ul style="list-style-type: none"> ○ One or more molds can be used during the surgery. For example, in the hip, a mold can be initially applied to the proximal femur that closely approximates the 3D anatomy prior to the resection of the femoral head. The mold can include an opening to accommodate a saw (see FIGS. 28-29). The opening is positioned to achieve an optimally placed surgical cut for subsequent reaming and placement of the prosthesis. A second mold can then be applied to the proximal femur after the surgical cut has been made. The second mold can be useful for guiding the direction of a reamer prior to placement of the prosthesis. As can be seen in this, as well as in other examples, molds can be made for joints prior to any surgical intervention. However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures. • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be

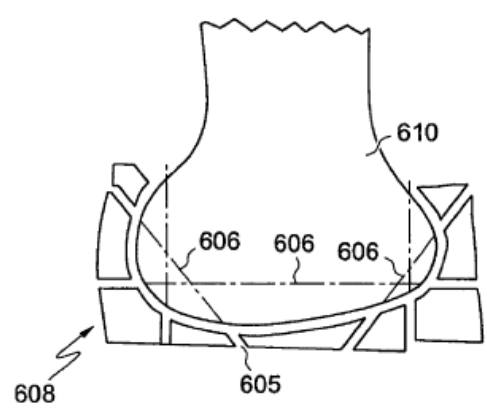
Claims of US 8,623,026	Invalidity Contentions
	<p>obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0277] <ul style="list-style-type: none"> ○ In another embodiment, a frame can be applied to the bone or the cartilage in areas other than the diseased bone or cartilage. The frame can include holders and guides for surgical instruments. The frame can be attached to one or preferably more previously defined anatomic reference points. Alternatively, the position of the frame can be cross-registered relative to one, or more, anatomic landmarks, using an imaging test or intraoperative measurement, for example one or more fluoroscopic images acquired intraoperatively. One or more electronic images or intraoperative measurements including using mechanical devices can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to move one or more of the holders or guides for surgical instruments. Typically, a position will be chosen that will result in a surgically or anatomically desirable cut plane or drill hole orientation for subsequent placement of an articular repair system. Information about other joints or axis and alignment

Claims of US 8,623,026	Invalidity Contentions
	<p>information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0287] <ul style="list-style-type: none"> ○ The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical tool can include one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface facing the surgical tool and, accordingly, will form a mirror image impression of the surface upon hardening, thereby recreating a normal or near normal articular surface. In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0291] <ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.

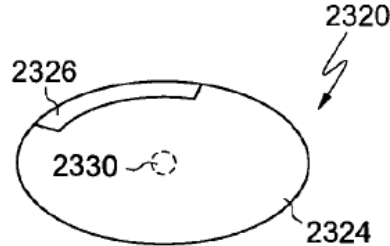
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0292] <ul style="list-style-type: none"> ○ Thus, surgical tools described herein can also be designed and used to control drill alignment, depth and width, for example when preparing a site to receive an implant. For example, the tools described herein, which typically conform to the joint surface, can provide for improved drill alignment and more accurate placement of any implant. • [0068] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. 24B depicts, in crosssection, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone. • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone. • Figure 24A

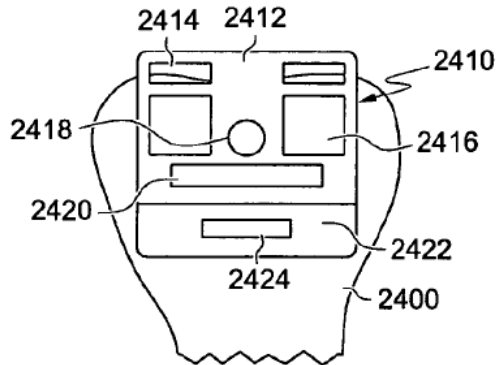
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p>  <p data-bbox="945 690 1113 738">FIG. 24A</p> <ul style="list-style-type: none"><li data-bbox="598 795 787 836">• Figure 24B

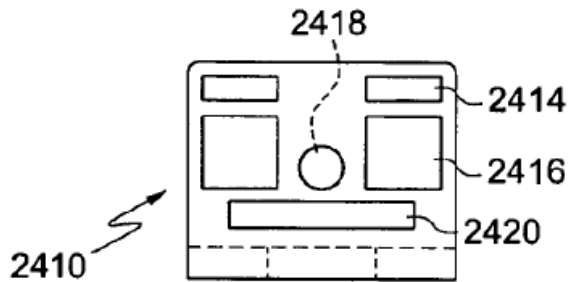
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730">  </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 836 1875 1209"> <p data-bbox="598 836 735 876">• [0294]</p> <p data-bbox="693 909 1875 1209">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.</p> <li data-bbox="598 1242 735 1282"> <p data-bbox="598 1242 735 1282">• [0296]</p>

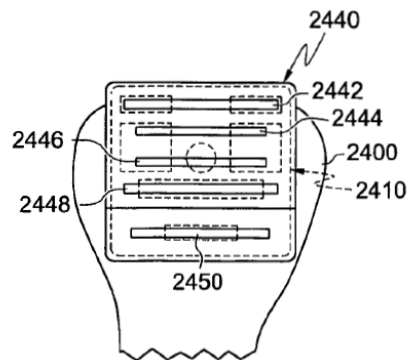
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The reusable exterior piece has a superior surface 2322 and an inferior surface 2324 that mates with the first piece 2310. The reusable exterior piece 2320 includes cutting guides 2328, to assist the surgeon in performing the tibial surface cut described above. As shown herein a plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the tibial cut. • [0300] <ul style="list-style-type: none"> ○ A guide plate 2326 is provided that extends along the side of at least a portion of the exterior piece 2320. The guide plate 2326 provides one or more slots or guides 2328 through which a saw blade can be inserted to achieve the cut desired of the tibial surface. Additionally, the slot, or guide, can be configured so that the saw blade cuts at a line perpendicular to the mechanical axis, or so that it cuts at a line that is perpendicular to the mechanical axis, but has a 4-7° slope in the sagittal plane to match the normal slope of the tibia. • Figures 25A & 25B

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="751 310 1631 774"> <p>FIG. 25A</p> <p>FIG. 25B</p> </div> <ul style="list-style-type: none"> • [0301] <ul style="list-style-type: none"> ○ Optionally, a central bore 2330 can be provided that, for example, enables a drill to ream a hole into the bone for the stem of the tibial component of the knee implant. • Figure 25C

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="772 349 1159 592">  </div> <p data-bbox="840 617 1029 665">FIG. 25C</p> <ul style="list-style-type: none"> <li data-bbox="598 747 724 779">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 820 1848 1291">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention. <li data-bbox="598 1331 756 1364">• Fig. 26A

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p>  <p data-bbox="919 711 1096 755">FIG. 26A</p> <ul style="list-style-type: none"> <li data-bbox="596 824 730 857">• [0316] <ul style="list-style-type: none"> <li data-bbox="688 894 1858 1073">○ FIG. 26D illustrates a top view of the first portion 2410. The bottom of the illustration corresponds to an anterior location relative to the knee joint. From the top view, each of the apertures is illustrated as described above. As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention. <li data-bbox="596 1117 793 1149">• Figure 26D

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 321 1323 600">  </div> <p data-bbox="982 633 1197 690">FIG. 26D</p> <ul style="list-style-type: none"> <li data-bbox="598 747 829 787">• [0317]-[0318] <ul style="list-style-type: none"> <li data-bbox="693 820 1858 1112">○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example, at a 45° angle. Other angles are also possible without departing from the scope of the invention. <li data-bbox="735 1153 1816 1226">As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer. <li data-bbox="598 1266 787 1307">• Figure 26E

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 300 1165 657">  </div> <p data-bbox="871 682 1018 722">FIG. 26E</p> <ul style="list-style-type: none"> <li data-bbox="598 787 735 820">• [0319] <ul style="list-style-type: none"> <li data-bbox="693 860 1858 1291">○ FIG. 26F illustrates a side view of the second, exterior, cutting block portion 2440. From the side view a single aperture 2450 is provided to access the femur cut. FIG. 26G is another side view of the second, exterior, portion 2440 showing the location and relative angles of the rectangular grooves. As evidenced from this view, the orientation of the grooves 2442, 2448 and 2450 is perpendicular to at least one surface of the second, exterior, portion 2440. The orientation of the grooves 2444, 2446 is at an angle that is not perpendicular to at least one surface of the second, exterior portion 2440. These grooves (2444, 2446) facilitate making the angled chamfer cuts to the femur. FIG. 26H is a top view of the second, exterior portion 2440. As will be appreciated by those of skill in the art, the location and orientation of the grooves will change depending upon the design of the femoral implant and the shape required of the femur to communicate with the implant. <li data-bbox="598 1339 892 1372">• Figures 26F & 26G

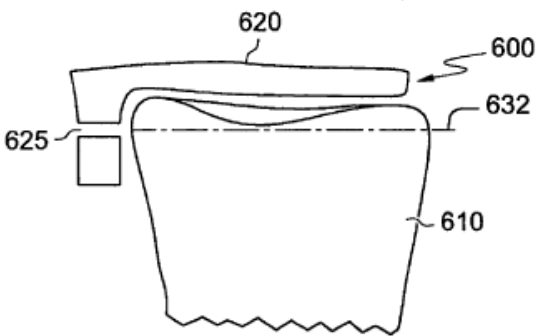
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 316 714 332">○</p> <div data-bbox="745 349 1680 527"> </div> <p data-bbox="787 560 945 609">FIG. 26F</p> <p data-bbox="1176 576 1333 625">FIG. 26G</p> <p data-bbox="1417 568 1585 617">FIG. 26H</p> <ul style="list-style-type: none"> <li data-bbox="598 706 735 738">• [0042] <ul style="list-style-type: none"> <li data-bbox="693 779 1858 1031">○ The invention is also directed to tools. A is disclosed that tool comprises: a mold having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block. Another tool is disclosed that is formed at least partially in situ and comprises: a mold formed in situ using at least one of an inflatable hollow device or a retaining device to conform to the joint surface on at least one surface having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block. <li data-bbox="598 1071 735 1104">• [0325] <ul style="list-style-type: none"> <li data-bbox="693 1144 1858 1364">○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to

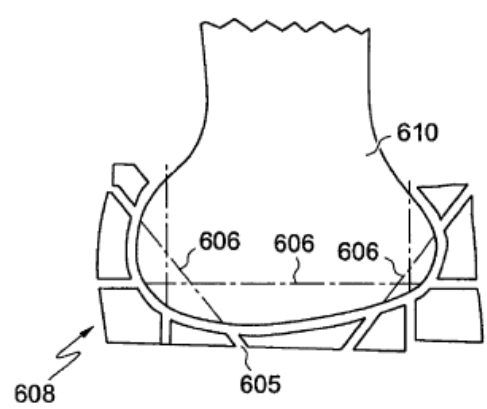
Claims of US 8,623,026	Invalidity Contentions
	<p>accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown.</p> <ul style="list-style-type: none"> • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A. The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div data-bbox="743 824 1005 1133"> <p style="text-align: center;">FIG. 27A</p> </div> <div data-bbox="1037 906 1341 1076"> <p style="text-align: center;">FIG. 27B</p> </div> <div data-bbox="1352 954 1751 1141"> <p style="text-align: center;">FIG. 27C</p> </div> </div> • Claim 48 <ul style="list-style-type: none"> ○ A tool formed at least partially in situ comprising:

Claims of US 8,623,026	Invalidity Contentions
	<p>a mold formed in situ using at least one of an inflatable hollow device or a retaining device to conform to the joint surface on at least one surface having a surface for engaging a joint surface; a block that communicates with the mold; and at least one guide aperture in the block.</p> <ul style="list-style-type: none"> • [0037] <ul style="list-style-type: none"> ○ In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool comprising one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint). In certain embodiments, the tool comprises Lucite silastic and/or other polymers or suitable materials. The tool can be re-useable or single-use. The tool can be comprised of a single component or multiple components. In certain embodiments, the tool comprises an array of adjustable, closely spaced pins. In any embodiments described herein, the surgical tool can be designed to further comprise an aperture therein, for example one or more apertures having dimensions (e.g., diameter, depth, etc.) smaller or equal to one or more dimensions of the implant and/or one or more apertures adapted to receive one or more injectables. Any of the tools described herein can further include one or more curable (hardening) materials or compositions, for example that are injected through one or more apertures in the tool and which solidify to form an impression of the articular surface. <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with</p>

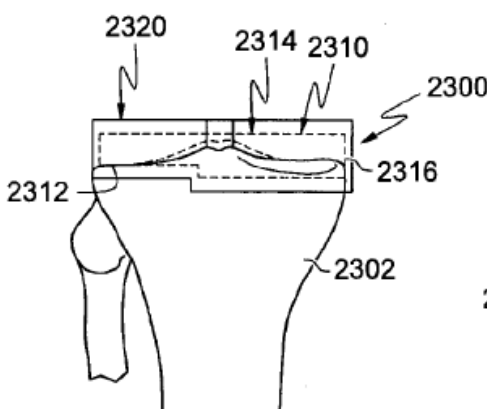
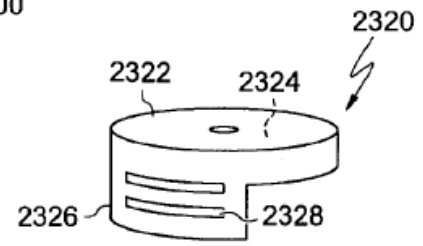
Claims of US 8,623,026	Invalidity Contentions
	<p>respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] (“The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited</p>

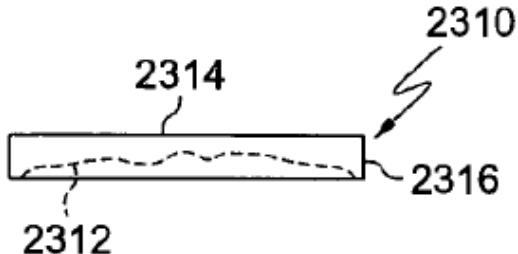
Claims of US 8,623,026	Invalidity Contentions
	to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).
[15.C.ii] wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0068] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. 24B depicts, in crosssection, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone. • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone. • Figure 24A

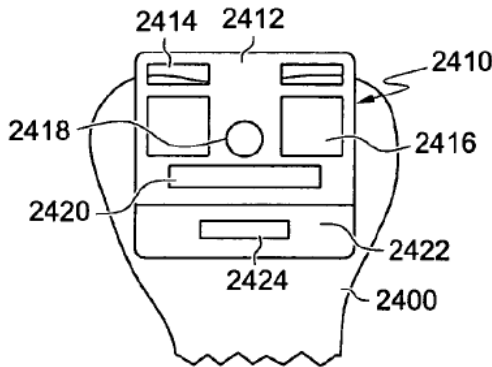
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 316 714 332">○</p>  <p data-bbox="945 730 1113 771">FIG. 24A</p> <ul style="list-style-type: none"><li data-bbox="598 836 787 868">• Figure 24B

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730">  </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 836 735 876">• [0294] <li data-bbox="693 909 1858 1209">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface. <li data-bbox="598 1242 735 1282">• [0069]

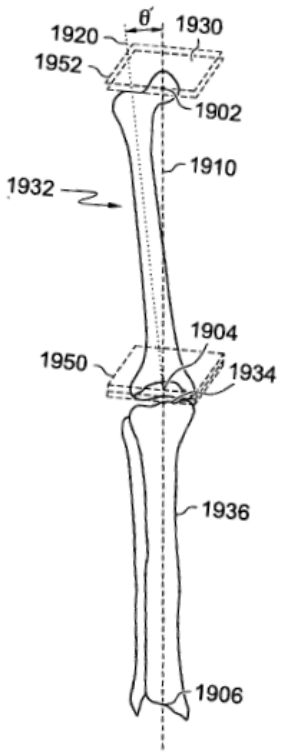
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ FIGS. 25A-Q illustrate tibial cutting blocks and molds used to create a surface perpendicular to the anatomic axis for receiving the tibial portion of a knee implant. • [0295] <ul style="list-style-type: none"> ○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. • [0296] <ul style="list-style-type: none"> ○ The reusable exterior piece has a superior surface 2322 and an inferior surface 2324 that mates with the first piece 2310. The reusable exterior piece 2320 includes cutting guides 2328, to assist the surgeon in performing the tibial surface cut described above. As shown herein a plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the tibial cut. • [0300] <ul style="list-style-type: none"> ○ A guide plate 2326 is provided that extends along the side of at least a portion of the exterior piece 2320. The guide plate 2326 provides one or more slots or guides 2328 through which a saw blade can be inserted to achieve the cut desired of the tibial surface. Additionally, the slot, or guide, can be configured so that the saw blade cuts at a line perpendicular to the mechanical axis, or so that it cuts at a line that is

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	<p>perpendicular to the mechanical axis, but has a 4-7° slope in the sagittal plane to match the normal slope of the tibia.</p> <ul style="list-style-type: none"> • Figures 25A & 25B <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p style="text-align: center;">FIG. 25A</p> <p style="text-align: center;">FIG. 25B</p> <ul style="list-style-type: none"> • [0297] <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. • Figure 25E

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 341 1270 592">  </div> <p data-bbox="840 633 1102 698">FIG. 25E</p> <ul style="list-style-type: none"> <li data-bbox="598 763 735 803">• [0070] <ul style="list-style-type: none"> <li data-bbox="693 836 1795 909">○ FIGS. 26A-O illustrate femur cutting blocks and molds used to create a surface for receiving the femoral portion of a knee implant. <li data-bbox="598 950 735 990">• [0312] <ul style="list-style-type: none"> <li data-bbox="693 1023 1816 1128">○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. <li data-bbox="598 1169 735 1209">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 1242 1837 1347">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures

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	<p>2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> Fig. 26A <ul style="list-style-type: none">  [0253]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none">○ Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.• [0065]<ul style="list-style-type: none">○ FIG. 21A illustrates a femur, tibia and fibula along with the mechanical and anatomic axes. FIGS. 21B-E illustrate the tibia with the anatomic and mechanical axis used to create a cutting plane along with a cut femur and tibia. FIG. 21F illustrates the proximal end of the femur including the head of the femur.• Figure 21A

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	<p data-bbox="693 276 714 300">○</p>  <ul style="list-style-type: none"> <li data-bbox="598 1112 735 1144">• [0254] <ul style="list-style-type: none"> <li data-bbox="693 1185 1848 1323">○ As shown in FIG. 21A, the center of the hip 1902 (located at the head 1930 of the femur 1932), the center of the knee 1904 (located at the notch where the intercondylar tubercle 1934 of the tibia 1936 meet the femur) and ankle 1906 lie approximately in a straight line 1910 which defines the mechanical axis of the lower extremity. The

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	<p>anatomic axis 1920 aligns 5-7° offset 8 from the mechanical axis in the valgus, or outward, direction.</p> <ul style="list-style-type: none"> • [0255] <ul style="list-style-type: none"> ○ The long axis of the tibia 1936 is collinear with the mechanical axis of the lower extremity 1910. From a threedimensional perspective, the lower extremity of the body ideally functions within a single plane known as the median anterior-posterior plane (MAP-plane) throughout the flexion-extension arc. In order to accomplish this, the femoral head 1930, the mechanical axis of the femur, the patellar groove, the intercondylar notch, the patellar articular crest, the tibia and the ankle remain within the MAP-plane during the flexion-extension movement. During movement, the tibia rotates as the knee flexes and extends in the epicondylar axis which is perpendicular to the MAP-plane. • [0257] <ul style="list-style-type: none"> ○ With disease and malfunction of the knee, alignment of the anatomic axis is altered. Performing a total knee arthroplasty is one solution for correcting a diseased knee. Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee. The resections should be made to enable the installed artificial knee to achieve flexion-extension movement within the MAP-plane and to optimize the patient's anatomical and mechanical axis of the lower extremity. • [0258] <ul style="list-style-type: none"> ○ First, the tibia 1930 is resected to create a flat surface to accept the tibial component of the implant. In most cases, the tibial surface is resected perpendicular to the long axis

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	<p>of the tibia in the coronal plane, but is typically sloped 4-7° posteriorly in the sagittal plane to match the normal slope of the tibia. As will be appreciated by those of skill in the art, the sagittal slope can be 0° where the device to be implanted does not require a sloped tibial cut. The resection line 1958 is perpendicular to the mechanical axis 1910, but the angle between the resection line and the surface plane of the plateau 1960 varies depending on the amount of damage to the knee.</p> <ul style="list-style-type: none"> • [0259] <ul style="list-style-type: none"> ○ FIGS. 21B-D illustrate an anterior view of a resection of an anatomically normal tibial component, a tibial component in a varus knee, and a tibial component in a valgus knee, respectively. In each figure, the mechanical axis 1910 extends vertically through the bone and the resection line 1958 is perpendicular to the mechanical axis 1910 in the coronal plane, varying from the surface line formed by the joint depending on the amount of damage to the joint. FIG. 21B illustrates a normal knee wherein the line corresponding to the surface of the joint 1960 is parallel to the resection line 1958. FIG. 21C illustrates a varus knee wherein the line corresponding to the surface of the joint 1960 is not parallel to the resection line 1958. FIG. 21D illustrates a valgus knee wherein the line corresponding to the surface of the joint 1960 is not parallel to the resection line 1958. • [0260] <ul style="list-style-type: none"> ○ Once the tibial surface has been prepared, the surgeon turns to preparing the femoral condyle. • [0261] <ul style="list-style-type: none"> ○ The plateau of the femur 1970 is resected to provide flat surfaces that communicate with the interior of the femoral prosthesis. The cuts made to the femur are based on the

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	<p>overall height of the gap to be created between the tibia and the femur. Typically, a 20 mm gap is desirable to provide the implanted prosthesis adequate room to achieve full range of motion. The bone is resected at a 5-7° angle valgus to the mechanical axis of the femur. Resected surface 1972 forms a flat plane with an angular relationship to adjoining surfaces 1974, 1976. The angle θ', θ'' between the surfaces 1972-1974, and 1972-1976 varies according to the design of the implant.</p> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C

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	<p data-bbox="693 276 714 300">○</p> <div data-bbox="743 305 1005 613"> </div> <p data-bbox="802 630 919 662">FIG. 27A</p> <div data-bbox="1041 386 1339 557"> </div> <p data-bbox="1102 589 1220 621">FIG. 27B</p> <div data-bbox="1360 443 1749 613"> </div> <p data-bbox="1451 621 1598 662">FIG. 27C</p> <ul style="list-style-type: none"> <li data-bbox="598 743 730 776">• [0088] <ul style="list-style-type: none"> <li data-bbox="693 816 1848 1255">○ Imaging can be used to determine the anatomical and biomechanical axes of an extremity associated with a joint. Suitable tests include, for example, an x-ray, or an x-ray combined with an MRI. Typically, anatomical landmarks are identified on the imaging test results (e.g., the x-ray film) and those landmarks are then utilized to directly or indirectly determine the desired axes. Thus, for example, if surgery is contemplated in a hip joint, knee joint, or ankle joint, an x-ray can be obtained. This x-ray can be a weightbearing film of the extremity, for example, a full-length leg film taken while the patient is standing. This film can be used to determine the femoral and tibial anatomical axes and to estimate the biomechanical axes. As will be appreciated by those of skill in the art, these processes for identifying, e.g., anatomical and biomechanical axis of the joint can be applied to other joints without departing from the scope of the invention. <li data-bbox="598 1295 730 1328">• [0089]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Anatomical and biomechanical axes can also be determined using other imaging modalities, including but not limited to, computed tomography and MRI. For example, a CT scan can be obtained through the hip joint, the knee joint, and the ankle joint. Optionally, the scan can be reformatted in the sagittal, coronal, or other planes. The CT images can then be utilized to identify anatomical landmarks and to determine the anatomical and biomechanical axes of the hip joint, knee joint, and/or ankle joint. Similarly, an MRI scan can be obtained for this purpose. For example, an MRI scan of the thigh and pelvic region can be obtained using a body coil or a torso phased array coil. A high resolution scan of the knee joint can be obtained using a dedicated extremity coil. A scan of the calf/tibia region and the ankle joint can be obtained again using a body coil or a torso phased array coil. Anatomical landmarks can be identified in each joint on these scans and the anatomical and biomechanical axes can be estimated using this information. • [0091] <ul style="list-style-type: none"> ○ The biomechanical axis can be defined as the axis going from the center of the femoral head, between the condylar surfaces and through the ankle joint. • [0093] <ul style="list-style-type: none"> ○ The angles of the anatomical structures of the proximal and distal femur also show a certain variability level (i.e. standard deviation) comparable with the varus or valgus angle or the angle between the anatomical femoral axis and the biomechanical axis (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Slaten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering."Med. Eng. and Phys. 24 (2002) 617-622). Thus, a preferred approach for assessing the axes is based on CT scans of the hip, knee and ankle joint or femur rather than only of the knee region.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0098] <ul style="list-style-type: none"> ○ Identification of landmarks of interest like the centroid of the tibial shaft, the ankle joint, the intercondylar notch and the centroid of the femoral head can be performed. The biomechanical axis can be defined as the line connecting the proximal and the distal centroids, i.e. the femoral head centroid, the tibial or ankle joint centroid. The position of the intercondylar notch can be used for evaluation of possible deviations, errors or deformations including varus and valgus deformity. • [0099] <ul style="list-style-type: none"> ○ In one embodiment, multiple imaging tests can be combined. For example, the anatomical and biomechanical axes can be estimated using a weight-bearing x-ray of the extremity or portions of the extremity. The anatomical information derived in this fashion can then be combined with a CT or MRI scan of one or more joints, such as a hip, knee, or ankle joint. Landmarks seen on radiography can then, for example, be cross-referenced on the CT or MRI scan. Axis measurements performed on radiography can be subsequently applied to the CT or MRI scans or other imaging modalities. Similarly, the information obtained from a CT scan can be compared with that obtained with an MRI or ultrasound scan. In one embodiment, image fusion of different imaging modalities can be performed. For example, if surgery is contemplated in a knee joint, a full-length weight-bearing x-ray of the lower extremity can be obtained. This can be supplemented by a spiral CT scan, optionally with intra-articular contrast of the knee joint providing high resolution three-dimensional anatomical characterization of the knee anatomy even including the menisci and cartilage. This information, along with the axis information provided by the radiograph can be utilized to select or derive therapies, such as implants or surgical instruments. • [0278]

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	<ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints

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	<p>or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0267] <ul style="list-style-type: none"> ○ Typically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general instrument orientation for subsequent placement of an articular repair system or for facilitating placement of the articular repair system. Moreover, the device can be designed so that the depth of the drill, reamer or other surgical instrument can be controlled, e.g., the drill cannot go any deeper into the tissue than defined by the device, and the size of the hole in the block can be designed to essentially match the size of the implant. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. • <i>See also</i> [0090], [0092], [0094]-[0097], [0256], [0291] <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] ("The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those</p>

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	<p>skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>
16. The system of claim 15, wherein the at least one guide includes at least one of the features selected from	Berez discloses (explicitly, implicitly, and inherently) and also renders obvious the system of claim 15, wherein the at least one guide includes at least one of the features selected from the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting

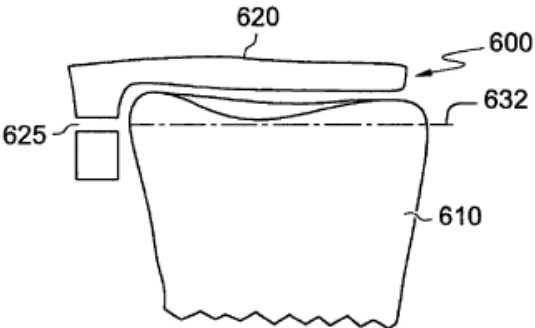
Claims of US 8,623,026	Invalidity Contentions
<p>the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting plane.</p>	<p>plane, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>See analysis and material cited for Claim 15, above. As further examples, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0266] <ul style="list-style-type: none"> ○ Mechanical devices can be used for surgical assistance (e.g., surgical tools), for example using gels, molds, plastics or metal. One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be utilized to either shape the device, e.g. using a CAD/CAM technique, to be adapted to a patient's articular anatomy or, alternatively, to select a typically pre-made device that has a good fit with a patient's articular anatomy. The device can have a surface and shape that will match all or portions of the articular or bone surface and shape, e.g. similar to a "mirror image." The device can include apertures, slots and/or holes to accommodate surgical instruments such as drills, reamers, curettes, k-wires, screws and saws. • [0267] <ul style="list-style-type: none"> ○ Typically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general instrument orientation for subsequent placement of an articular repair system or for facilitating placement of the articular repair system. Moreover, the device can be designed so that the depth of the drill, reamer or other surgical instrument can be controlled, e.g., the drill cannot go any deeper into the tissue than defined by the device, and the size of the hole in the block can be designed to essentially match the size of the implant. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the

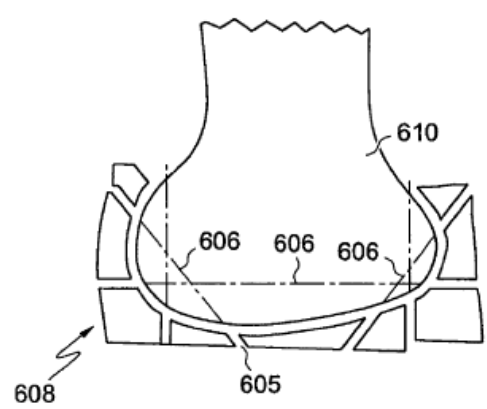
Claims of US 8,623,026	Invalidity Contentions
	<p>position of these slots or holes. Alternatively, the openings in the device can be made larger than needed to accommodate these instruments. The device can also be configured to conform to the articular shape. The apertures, or openings, provided can be wide enough to allow for varying the position or angle of the surgical instrument, e.g., reamers, saws, drills, curettes and other surgical instruments. An instrument guide, typically comprised of a relatively hard material, can then be applied to the device. The device helps orient the instrument guide relative to the three-dimensional anatomy of the joint.</p> <ul style="list-style-type: none"> • [0274] <ul style="list-style-type: none"> ○ One or more molds can be used during the surgery. For example, in the hip, a mold can be initially applied to the proximal femur that closely approximates the 3D anatomy prior to the resection of the femoral head. The mold can include an opening to accommodate a saw (see FIGS. 28-29). The opening is positioned to achieve an optimally placed surgical cut for subsequent reaming and placement of the prosthesis. A second mold can then be applied to the proximal femur after the surgical cut has been made. The second mold can be useful for guiding the direction of a reamer prior to placement of the prosthesis. As can be seen in this, as well as in other examples, molds can be made for joints prior to any surgical intervention. However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures. • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be

Claims of US 8,623,026	Invalidity Contentions
	<p>obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0291]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0292] <ul style="list-style-type: none"> ○ Thus, surgical tools described herein can also be designed and used to control drill alignment, depth and width, for example when preparing a site to receive an implant. For example, the tools described herein, which typically conform to the joint surface, can provide for improved drill alignment and more accurate placement of any implant. • [0068] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. 24B depicts, in crosssection, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone. • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone. • Figure 24A

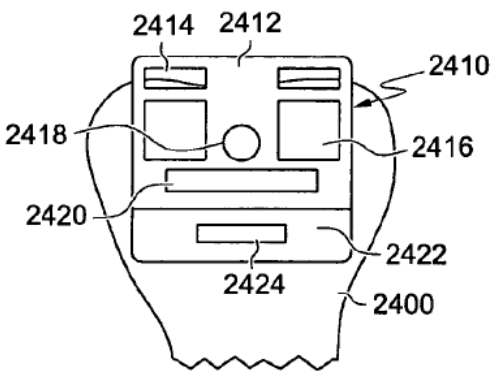
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p>  <p data-bbox="947 695 1108 737">FIG. 24A</p> <ul style="list-style-type: none"><li data-bbox="596 802 789 834">• Figure 24B

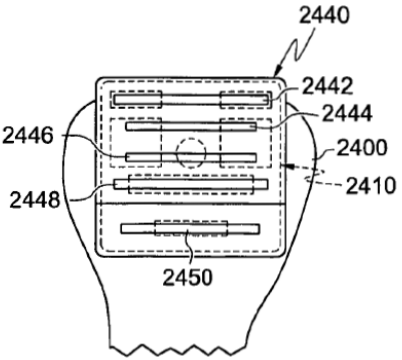
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730">  </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 836 1858 1209"> <p data-bbox="598 836 735 876">• [0294]</p> <p data-bbox="693 909 1858 1209">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.</p> <li data-bbox="598 1242 735 1282"> <p data-bbox="598 1242 735 1282">• [0296]</p>

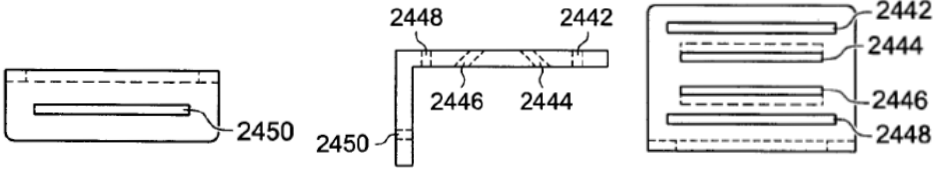
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The reusable exterior piece has a superior surface 2322 and an inferior surface 2324 that mates with the first piece 2310. The reusable exterior piece 2320 includes cutting guides 2328, to assist the surgeon in performing the tibial surface cut described above. As shown herein a plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the tibial cut. • [0300] <ul style="list-style-type: none"> ○ A guide plate 2326 is provided that extends along the side of at least a portion of the exterior piece 2320. The guide plate 2326 provides one or more slots or guides 2328 through which a saw blade can be inserted to achieve the cut desired of the tibial surface. Additionally, the slot, or guide, can be configured so that the saw blade cuts at a line perpendicular to the mechanical axis, or so that it cuts at a line that is perpendicular to the mechanical axis, but has a 4-7° slope in the sagittal plane to match the normal slope of the tibia. • Figures 25A & 25B

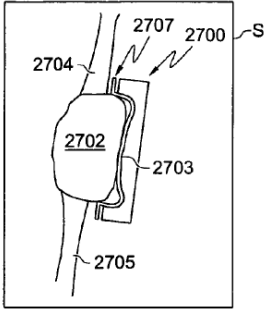
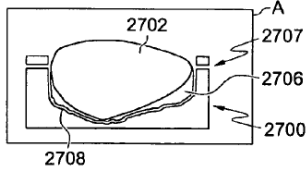
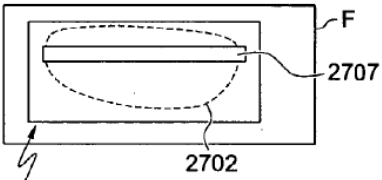
Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="753 306 1631 774" data-label="Image"> <p>FIG. 25A</p> <p>FIG. 25B</p> <ul style="list-style-type: none"> • [0301] <ul style="list-style-type: none"> ○ Optionally, a central bore 2330 can be provided that, for example, enables a drill to ream a hole into the bone for the stem of the tibial component of the knee implant. • Figure 25C </div>

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="774 344 1161 591"> </div> <p data-bbox="842 618 1031 667">FIG. 25C</p> <ul style="list-style-type: none"> <li data-bbox="598 748 730 781">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 821 1856 1292">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention. <li data-bbox="598 1333 758 1365">• Fig. 26A

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p>  <p data-bbox="913 706 1102 755">FIG. 26A</p> <ul style="list-style-type: none"> <li data-bbox="598 820 829 852">• [0317]-[0318] <ul style="list-style-type: none"> <li data-bbox="693 893 1858 1185">○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example, at a 45° angle. Other angles are also possible without departing from the scope of the invention. <p data-bbox="735 1226 1816 1291">As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer.</p> <ul style="list-style-type: none"> <li data-bbox="598 1339 787 1372">• Figure 26E

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p>  <p>FIG. 26E</p> <ul style="list-style-type: none"> • [0319] <ul style="list-style-type: none"> ○ FIG. 26F illustrates a side view of the second, exterior, cutting block portion 2440. From the side view a single aperture 2450 is provided to access the femur cut. FIG. 26G is another side view of the second, exterior, portion 2440 showing the location and relative angles of the rectangular grooves. As evidenced from this view, the orientation of the grooves 2442, 2448 and 2450 is perpendicular to at least one surface of the second, exterior, portion 2440. The orientation of the grooves 2444, 2446 is at an angle that is not perpendicular to at least one surface of the second, exterior portion 2440. These grooves (2444, 2446) facilitate making the angled chamfer cuts to the femur. FIG. 26H is a top view of the second, exterior portion 2440. As will be appreciated by those of skill in the art, the location and orientation of the grooves will change depending upon the design of the femoral implant and the shape required of the femur to communicate with the implant.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • Figures 26F & 26G <ul style="list-style-type: none"> ○ <div style="text-align: center; margin: 20px 0;">  <div style="display: flex; justify-content: space-around; margin-top: 10px;"> FIG. 26F FIG. 26G FIG. 26H </div> </div> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A. The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a

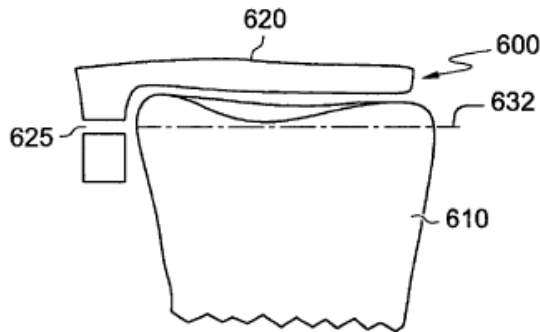
Claims of US 8,623,026	Invalidity Contentions
	<p>frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702.</p> <ul style="list-style-type: none"> Figures 27A, 27B & 27C <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  <p>FIG. 27A</p> </div> <div style="text-align: center;">  <p>FIG. 27B</p> </div> <div style="text-align: center;">  <p>FIG. 27C</p> </div> </div> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] ("The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>
23. The system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the	Berez discloses (explicitly, implicitly, and inherently) and also renders obvious the system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the first articular surface of the joint, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.

Claims of US 8,623,026	Invalidity Contentions
first articular surface of the joint.	<p>See analysis and material cited for Claim 15, above. As further examples, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141. • Figure 23

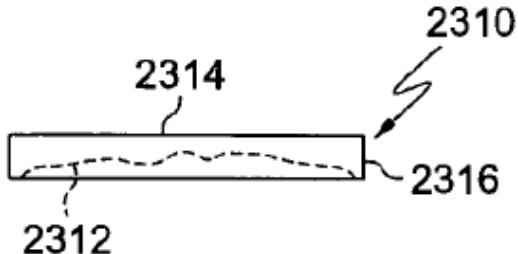
Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 --> 2142((Perform Implantation 2142)) </pre> <ul style="list-style-type: none"> • [0291]

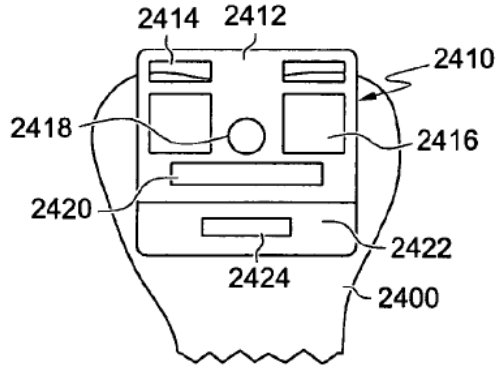
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times. • [0293]

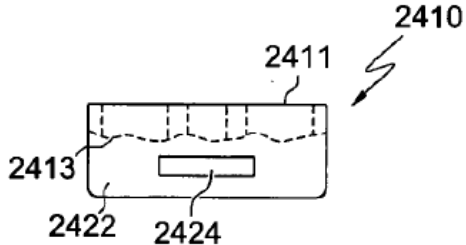
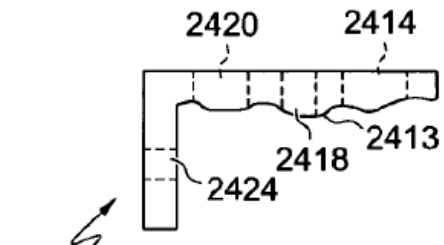
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none">○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone.• Figure 24A<ul style="list-style-type: none">○• Figure 24B

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730"> </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 844 735 876">• [0295] <ul style="list-style-type: none"> <li data-bbox="693 917 1848 1242">○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. <li data-bbox="598 1282 903 1323">• Figures 25A & 25B

Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <div data-bbox="753 306 1631 773" data-label="Image"> <p>FIG. 25A</p> <p>FIG. 25B</p> </div> <ul style="list-style-type: none"> • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci. • Figure 25E

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 341 1270 592">  </div> <p data-bbox="840 633 1102 698">FIG. 25E</p> <ul style="list-style-type: none"> <li data-bbox="598 763 735 803">• [0312] <ul style="list-style-type: none"> <li data-bbox="693 836 1816 950">○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. <li data-bbox="598 982 735 1023">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 1055 1848 1347">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut

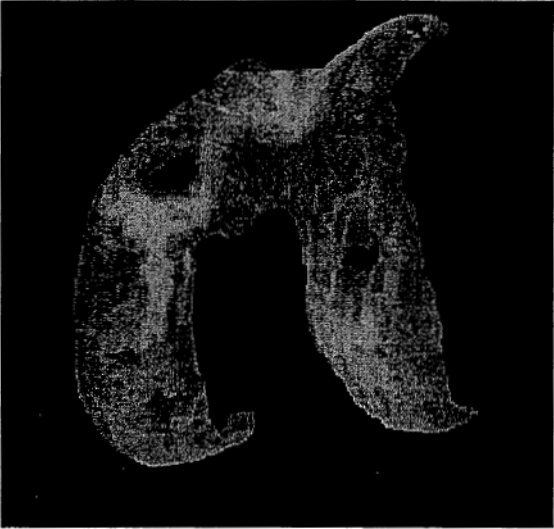
Claims of US 8,623,026	Invalidity Contentions
	<p>during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> • Fig. 26A <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26A</p> <ul style="list-style-type: none"> • [0314]-[0315] <ul style="list-style-type: none"> ○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur.

Claims of US 8,623,026	Invalidity Contentions
	<p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end; margin-top: 20px;"> <div style="text-align: center;">  <p>FIG. 26B</p> </div> <div style="text-align: center;">  <p>FIG. 26C</p> </div> </div> <ul style="list-style-type: none"> • [0317]-[0318] <ul style="list-style-type: none"> ○ Turning now to FIG. 26E, the femur 2400 with a first portion 2410 of the cutting block placed on the femur and a second, exterior, portion 2440 placed over the first portion 2410 is illustrated. The second, exterior, portion 2440 features a series of rectangular grooves (2442-2450) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. 21E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example,

Claims of US 8,623,026	Invalidity Contentions
	<p>at a 45° angle. Other angles are also possible without departing from the scope of the invention.</p> <p>As shown by the dashed lines, the grooves (2442-2450) of the second portion 2440, overlay the apertures of the first layer.</p> <ul style="list-style-type: none"> • [0324] <ul style="list-style-type: none"> ○ As illustrated in FIGS. 26N (sagittal view) and 26M (coronal view), the interior surface 2413 of the mold 2410 can include small teeth 2465 or extensions that can help stabilize the mold against the cartilage 2466 or subchondral bone 2467. • Figure 26N <ul style="list-style-type: none"> ○ <div data-bbox="735 841 1234 1144" data-label="Image"> </div> <p style="text-align: center;">FIG. 26N</p> <ul style="list-style-type: none"> • [0325]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="743 305 1008 613"> </div> <p data-bbox="802 630 924 662">FIG. 27A</p> <div data-bbox="1039 386 1344 560"> </div> <p data-bbox="1102 587 1224 620">FIG. 27B</p> <div data-bbox="1354 438 1753 625"> </div> <p data-bbox="1449 625 1606 657">FIG. 27C</p> <ul style="list-style-type: none"> <li data-bbox="598 711 730 743">• [0026] <ul style="list-style-type: none"> <li data-bbox="693 782 1843 928">○ In yet another aspect, the invention provides a method of determining the curvature of an articular surface, the method comprising the step of intraoperatively measuring the curvature of the articular surface using a mechanical probe. The articular surface can comprise cartilage and/or subchondral bone. <li data-bbox="598 971 730 1003">• [0100] <ul style="list-style-type: none"> <li data-bbox="693 1042 1852 1334">○ In certain embodiments, it may be desirable to characterize the shape and dimension of intra-articular structures, including subchondral bone or the cartilage. This can be done using a CT scan, preferably a spiral CT scan of one or more joints. The spiral CT scan can optionally be performed using intra-articular contrast. Alternatively, an MRI scan can be performed. If CT is utilized, a full spiral scan, or a few selected slices, can be obtained through neighboring joints. Typically, a full spiral scan providing full three-dimensional characterization would be obtained in the joint for which therapy is contemplated. If implants, or molds, for surgical instruments are selected or shaped,

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="741 272 1797 337">using this scan, the subchondral bone shape can be accurately determined from the resultant image data.</p> <ul style="list-style-type: none"><li data-bbox="598 386 730 418">• [0046]<ul style="list-style-type: none"><li data-bbox="695 459 1829 597">○ FIG. 2 is a color reproduction of a three-dimensional thickness map of the articular cartilage of the distal femur. Three-dimensional thickness maps can be generated, for example, from ultrasound, CT or MRI data. Dark holes within the substances of the cartilage indicate areas of full thickness cartilage loss.<li data-bbox="598 646 751 678">• Figure 2<ul style="list-style-type: none"><li data-bbox="695 686 716 711">○<li data-bbox="598 1287 730 1320">• [0103]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Alternatively, or in addition to, non-invasive imaging techniques described above, measurements of the size of an area of diseased cartilage or an area of cartilage loss, measurements of cartilage thickness and/or curvature of cartilage or bone can be obtained intraoperatively during arthroscopy or open arthrotomy. Intraoperative measurements can, but need not, involve actual contact with one or more areas of the articular surfaces. • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0168] <ul style="list-style-type: none"> ○ The balloon can be slowly injected with a self hardening or hardening material such as a polymer and even metals. The material is initially in a fluid or semi-fluid state. The material expands the balloon whereby the shape of the balloon will take substantially the shape of the articular surface(s) and other articular structures. The polymer will subsequently harden inside the balloon thereby substantially taking the shape of the

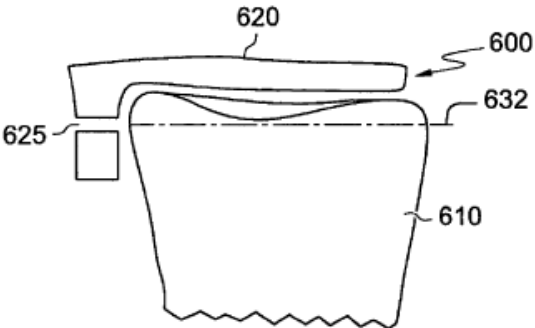
Claims of US 8,623,026	Invalidity Contentions
	<p>articular cavity and articular surface(s)/structures. The balloon can also be composed of a bio-resorbable material. The balloon can also be removed after the procedure.</p> <ul style="list-style-type: none"> • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] (“The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited</p>

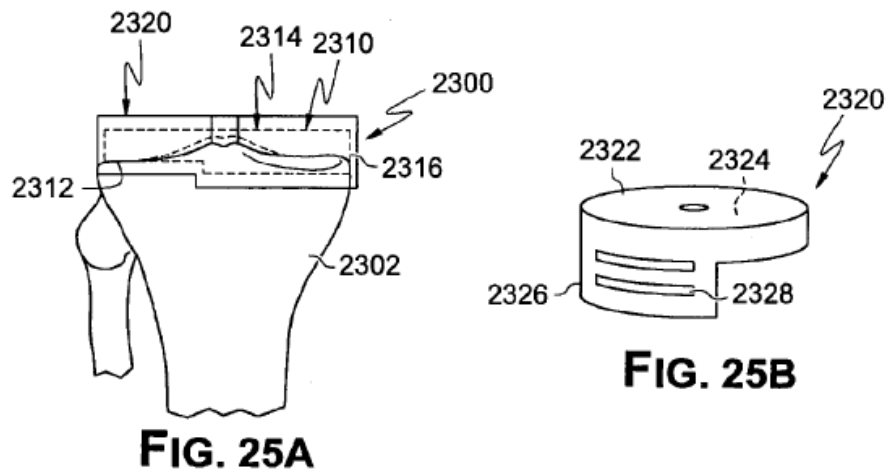
Claims of US 8,623,026	Invalidity Contentions
	to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).
[52-pre] A system for joint arthroplasty, the system comprising:	<p>To the extent the preamble is limiting, Berez discloses (explicitly, implicitly, and inherently) and also renders obvious a system for joint arthroplasty, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint. <i>See</i> analysis and material cited for claim 15-pre, above.</p> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA’s knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants’ Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants’ Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 15-pre, above.</p>
[52.A] a first template, the first template including:	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious a first template, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint. <i>See</i> analysis and material cited for claim 15.A, above.</p> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA’s knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants’ Invalidity Contentions, including but not limited to the particular exemplary references discussed with</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 15.A, above.</p>
<p>[52.B.i] at least one surface for engaging a first cartilage surface of a joint,</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious at least one surface for engaging a first cartilage surface of a joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p><i>See</i> analysis and material cited for claim 15.B.i, above. As further examples, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • [0291] <ul style="list-style-type: none"> ○ When a total knee arthroplasty is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of a knee joint, e.g. width of the femoral condyles, the tibial plateau etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT scan or an MRI scan or combinations thereof. The articular surface and shape as well as alignment information generated with the imaging test can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface or by attaching it to anatomic reference points on the bone or cartilage. The surgeon

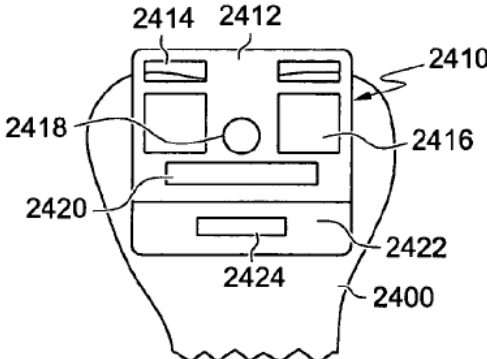
Claims of US 8,623,026	Invalidity Contentions
	<p>can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis malalignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.</p> <ul style="list-style-type: none"> • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone. • Figure 24A

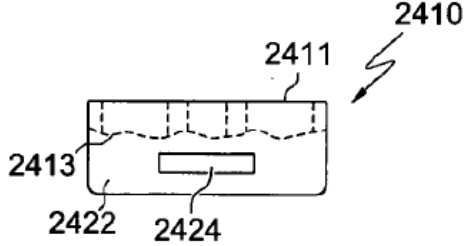
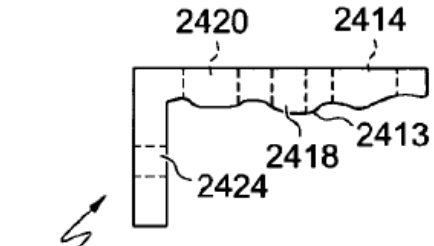
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p>  <p data-bbox="947 695 1108 737">FIG. 24A</p> <ul data-bbox="598 802 789 834" style="list-style-type: none">• Figure 24B

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730"> </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 836 735 876">• [0295] <ul style="list-style-type: none"> <li data-bbox="693 909 1848 1242">○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. <li data-bbox="598 1282 903 1323">• Figures 25A & 25B

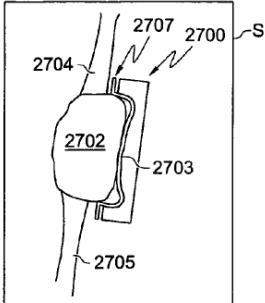
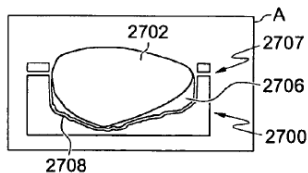
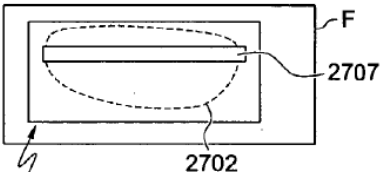
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="688 277 716 298">○</p> <div data-bbox="751 306 1631 773">  <p data-bbox="884 727 1066 773">FIG. 25A</p> <p data-bbox="1367 651 1549 696">FIG. 25B</p> </div> <ul style="list-style-type: none"> <li data-bbox="596 833 1848 1047"> <p data-bbox="596 833 730 862">• [0298]</p> <ul style="list-style-type: none"> <li data-bbox="688 902 1848 1047"> <p data-bbox="688 902 1848 1047">○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci.</p> <li data-bbox="596 1089 789 1122"> <p data-bbox="596 1089 789 1122">• Figure 25E</p>

Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 341 1270 592"> </div> <p data-bbox="840 633 1102 698">FIG. 25E</p> <ul style="list-style-type: none"> <li data-bbox="598 763 735 803">• [0312] <ul style="list-style-type: none"> <li data-bbox="693 836 1816 950">○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. <li data-bbox="598 982 735 1023">• [0313] <ul style="list-style-type: none"> <li data-bbox="693 1055 1837 1347">○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures 2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut

Claims of US 8,623,026	Invalidity Contentions
	<p>during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> • Fig. 26A <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26A</p> <ul style="list-style-type: none"> • [0314]-[0315] <ul style="list-style-type: none"> ○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur.

Claims of US 8,623,026	Invalidity Contentions
	<p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end; margin-top: 20px;"> <div style="text-align: center;">  <p>FIG. 26B</p> </div> <div style="text-align: center;">  <p>FIG. 26C</p> </div> </div> <ul style="list-style-type: none"> • [0324] <ul style="list-style-type: none"> ○ As illustrated in FIGS. 26N (sagittal view) and 26M (coronal view), the interior surface 2413 of the mold 2410 can include small teeth 2465 or extensions that can help stabilize the mold against the cartilage 2466 or subchondral bone 2467.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 26N <ul style="list-style-type: none"> ○ <div data-bbox="735 401 1232 704" data-label="Image"> </div> <p style="text-align: center;">FIG. 26N</p> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown. • [0326]

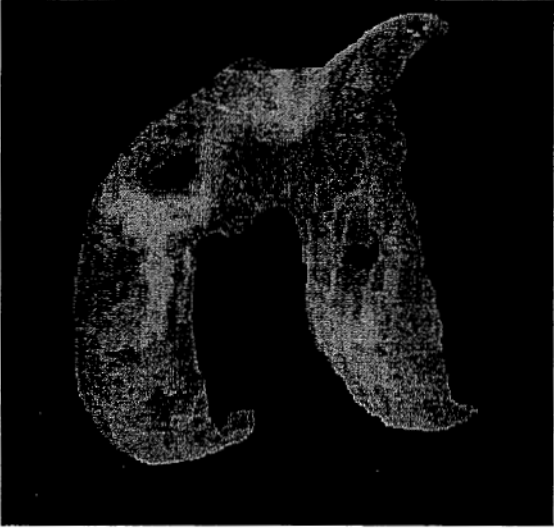
Claims of US 8,623,026	Invalidity Contentions
	<p>○ FIG. 27B is a view in the axial plane A The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702.</p> <p>• Figures 27A, 27B & 27C</p> <p>○</p> <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  <p>FIG. 27A</p> </div> <div style="text-align: center;">  <p>FIG. 27B</p> </div> <div style="text-align: center;">  <p>FIG. 27C</p> </div> </div> <p>• [0099]</p> <p>○ In one embodiment, multiple imaging tests can be combined. For example, the anatomical and biomechanical axes can be estimated using a weight-bearing x-ray of the extremity or portions of the extremity. The anatomical information derived in this fashion can then be combined with a CT or MRI scan of one or more joints, such as a hip, knee, or ankle joint. Landmarks seen on radiography can then, for example, be cross-referenced on the CT or MRI scan. Axis measurements performed on radiography can be subsequently applied to the CT or MRI scans or other imaging modalities. Similarly, the information obtained from a CT scan can be compared with that obtained with an MRI or ultrasound scan. In one embodiment, image fusion of</p>

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	<p>different imaging modalities can be performed. For example, if surgery is contemplated in a knee joint, a full-length weight-bearing x-ray of the lower extremity can be obtained. This can be supplemented by a spiral CT scan, optionally with intra-articular contrast of the knee joint providing high resolution three-dimensional anatomical characterization of the knee anatomy even including the menisci and cartilage. This information, along with the axis information provided by the radiograph can be utilized to select or derive therapies, such as implants or surgical instruments.</p> <ul style="list-style-type: none"> • [0100] <ul style="list-style-type: none"> ○ In certain embodiments, it may be desirable to characterize the shape and dimension of intra-articular structures, including subchondral bone or the cartilage. This can be done using a CT scan, preferably a spiral CT scan of one or more joints. The spiral CT scan can optionally be performed using intra-articular contrast. Alternatively, an MRI scan can be performed. If CT is utilized, a full spiral scan, or a few selected slices, can be obtained through neighboring joints. Typically, a full spiral scan providing full three-dimensional characterization would be obtained in the joint for which therapy is contemplated. If implants, or molds, for surgical instruments are selected or shaped, using this scan, the subchondral bone shape can be accurately determined from the resultant image data. • [0101] <ul style="list-style-type: none"> ○ Alternatively, however, the articular cartilage can be fully characterized by performing a spiral CT scan of the joint in the presence of intra-articular contrast or by performing an MRI scan using cartilage sensitive pulse sequences. • [0103]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Alternatively, or in addition to, non-invasive imaging techniques described above, measurements of the size of an area of diseased cartilage or an area of cartilage loss, measurements of cartilage thickness and/or curvature of cartilage or bone can be obtained intraoperatively during arthroscopy or open arthrotomy. Intraoperative measurements can, but need not, involve actual contact with one or more areas of the articular surfaces. • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141. • Figure 23

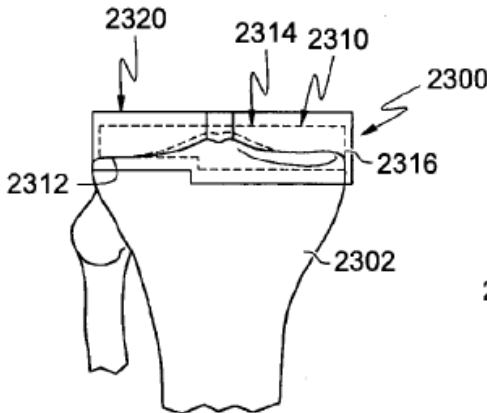
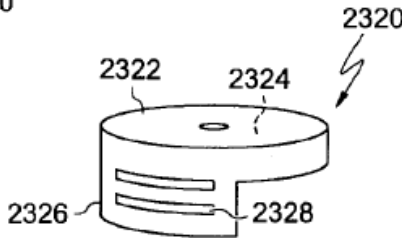
Claims of US 8,623,026	Invalidity Contentions
	<p>○</p> <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] -- Optional 2101 --> 2100 2100 --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 -- Optional 2121 --> 2120 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 -- Optional 2131 --> 2130 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 -- Optional 2133 --> 2132 2134 -- Optional 2135 --> 2134 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 -- Optional 2141 --> 2140 2140 --> 2142((Perform Implantation 2142)) 2102 --> 2100 </pre> <ul style="list-style-type: none"> • [0136]

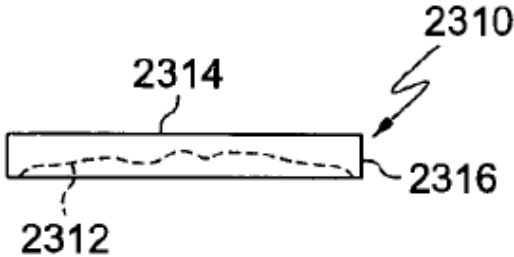
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Using information on thickness and curvature of the cartilage, a physical model of the surfaces of the articular cartilage and of the underlying bone can be created. This physical model can be representative of a limited area within the joint or it can encompass the entire joint. For example, in the knee joint, the physical model can encompass only the medial or lateral femoral condyle, both femoral condyles and the notch region, the medial tibial plateau, the lateral tibial plateau, the entire tibial plateau, the medial patella, the lateral patella, the entire patella or the entire joint. The location of a diseased area of cartilage can be determined, for example using a 3D coordinate system or a 3D Euclidian distance as described in WO 02/22014. • [0046] ○ FIG. 2 is a color reproduction of a three-dimensional thickness map of the articular cartilage of the distal femur. Three-dimensional thickness maps can be generated, for example, from ultrasound, CT or MRI data. Dark holes within the substances of the cartilage indicate areas of full thickness cartilage loss. • Figure 2

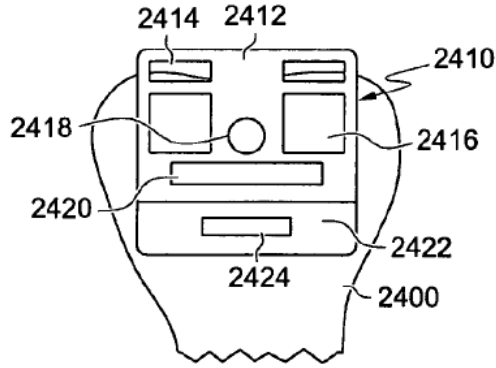
Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none">○ • [0275]<ul style="list-style-type: none">○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by

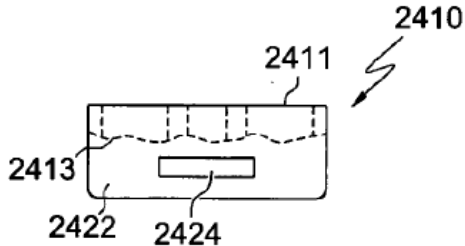
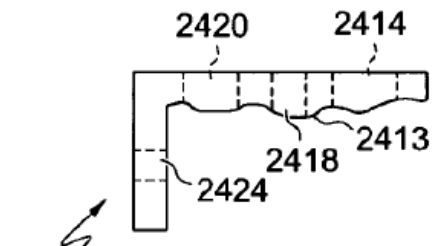
Claims of US 8,623,026	Invalidity Contentions
	<p>moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.</p> <ul style="list-style-type: none"> • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

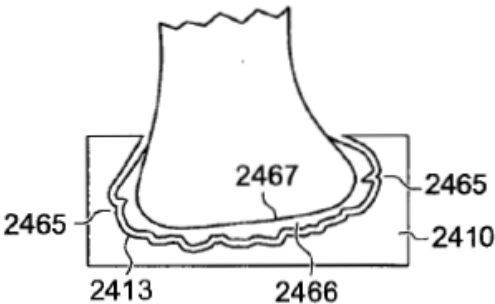
Claims of US 8,623,026	Invalidity Contentions
	<p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] (“The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.”); [0253] (“Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.”); [0274] (“However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures.”); [0289] (“Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention”); [0294] (“Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.”); [307] (“Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.”); [0316] (“As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>

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<p>[52.B.ii] the at least one surface being substantially a negative of portions of the first cartilage surface;</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious the at least one surface being substantially a negative of portions of the first cartilage surface, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p><i>See</i> analysis and material cited for claim 15.B.ii, above. As further examples, see the following illustrative citations to Berez:</p> <ul style="list-style-type: none"> • Figures 25A & 25B <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 25A</p> ○  <p style="text-align: center;">FIG. 25B</p> • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue

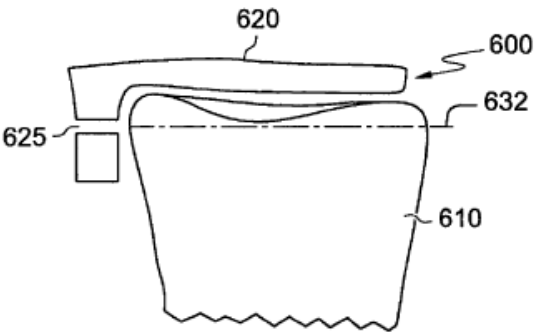
Claims of US 8,623,026	Invalidity Contentions
	<p>prior to applying the mold. Optionally, the interior surface 2312 of the mold can include shape information of portions or all of the menisci.</p> <ul style="list-style-type: none"> • Figure 25E <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 25E</p> <ul style="list-style-type: none"> • [0312] <ul style="list-style-type: none"> ○ Turning now to FIG. 26, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment. • [0313] <ul style="list-style-type: none"> ○ FIG. 26A illustrates the femur 2400 with a first portion 2410 of the mold placed thereon. In this depiction, the top surface of the mold 2412 is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures

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	<p>2414, a pair of square apertures 2416, a central bore aperture 2418 and a long rectangular aperture 2420. The side surface 2422 of the first portion 2410 also has a rectangular aperture 2424. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.</p> <ul style="list-style-type: none"> Fig. 26A <ul style="list-style-type: none">  [0314]-[0315]

Claims of US 8,623,026	Invalidity Contentions
	<p>○ FIG. 26B illustrates a side view of the first portion 2410 from the perspective of the side surface 2422 illustrating the aperture 2424. As illustrated, the exterior surface 2411 has a uniform surface which is flat, or relatively flat configuration while the interior surface 2413 has an irregular surface that conforms, or substantially conforms, with the surface of the femur.</p> <p>FIG. 26C illustrates another side view of the first, patient specific molded, portion 2410, more particularly illustrating the irregular surface 2413 of the interior. FIG. 26D illustrates the first portion 2410 from a top view. The center bore aperture 2418 is optionally provided to facilitate positioning the first piece and to prevent central rotation.</p> <ul style="list-style-type: none"> • Figures 26B-26C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  <p>FIG. 26B</p> </div> <div style="text-align: center;">  <p>FIG. 26C</p> </div> </div> <ul style="list-style-type: none"> • [0324]

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ As illustrated in FIGS. 26N (sagittal view) and 26M (coronal view), the interior surface 2413 of the mold 2410 can include small teeth 2465 or extensions that can help stabilize the mold against the cartilage 2466 or subchondral bone 2467. • Figure 26N <ul style="list-style-type: none"> ○  <p style="text-align: center;">FIG. 26N</p> <ul style="list-style-type: none"> • [0325] <ul style="list-style-type: none"> ○ Turning now to FIG. 27, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. 27A-C illustrates the patellar cutting block 2700 in conjunction with a patella 2702 that has not been resected. In this depiction, the cutting block 2700 can consist of only one piece or a plurality of pieces, if desired. The inner surface 2703 is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella 2702. Small openings are present 2707 to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine

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	<p>adjustments. FIG. 27A is a view in the sagittal plane S. The quadriceps tendon 2704 and patellar tendon 2705 are shown.</p> <ul style="list-style-type: none"> • [0326] <ul style="list-style-type: none"> ○ FIG. 27B is a view in the axial plane A. The cartilage 2706 is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. 27C is a frontal view F of the mold demonstrating the opening for the saw 2707. The dashed line indicates the relative position of the patella 2702. • Figures 27A, 27B & 27C <ul style="list-style-type: none"> ○ <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div data-bbox="745 751 1008 1057"> </div> <div data-bbox="1039 829 1344 1000"> </div> <div data-bbox="1360 883 1749 1057"> </div> </div> • [0293] <ul style="list-style-type: none"> ○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the

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	<p data-bbox="741 272 1822 342">proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone.</p> <ul style="list-style-type: none"><li data-bbox="598 383 793 415">• Figure 24A<ul style="list-style-type: none"><li data-bbox="695 464 711 483">○<li data-bbox="598 984 793 1016">• Figure 24B <p data-bbox="947 878 1108 922">FIG. 24A</p>

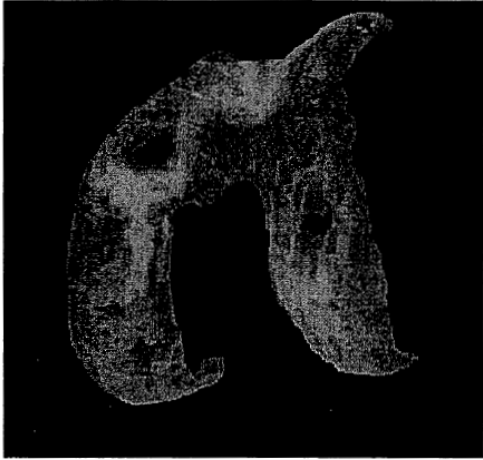
Claims of US 8,623,026	Invalidity Contentions
	<p data-bbox="693 276 714 300">○</p> <div data-bbox="756 324 1239 730"> </div> <p data-bbox="934 738 1102 787">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="598 836 1858 1242"> <p data-bbox="598 836 735 876">• [0295]</p> <p data-bbox="693 909 1858 1242">○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone.</p> <li data-bbox="598 1315 735 1356"> <p data-bbox="598 1315 735 1356">• [0099]</p>

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In one embodiment, multiple imaging tests can be combined. For example, the anatomical and biomechanical axes can be estimated using a weight-bearing x-ray of the extremity or portions of the extremity. The anatomical information derived in this fashion can then be combined with a CT or MRI scan of one or more joints, such as a hip, knee, or ankle joint. Landmarks seen on radiography can then, for example, be cross-referenced on the CT or MRI scan. Axis measurements performed on radiography can be subsequently applied to the CT or MRI scans or other imaging modalities. Similarly, the information obtained from a CT scan can be compared with that obtained with an MRI or ultrasound scan. In one embodiment, image fusion of different imaging modalities can be performed. For example, if surgery is contemplated in a knee joint, a full-length weight-bearing x-ray of the lower extremity can be obtained. This can be supplemented by a spiral CT scan, optionally with intra-articular contrast of the knee joint providing high resolution three-dimensional anatomical characterization of the knee anatomy even including the menisci and cartilage. This information, along with the axis information provided by the radiograph can be utilized to select or derive therapies, such as implants or surgical instruments. • [0100] <ul style="list-style-type: none"> ○ In certain embodiments, it may be desirable to characterize the shape and dimension of intra-articular structures, including subchondral bone or the cartilage. This can be done using a CT scan, preferably a spiral CT scan of one or more joints. The spiral CT scan can optionally be performed using intra-articular contrast. Alternatively, an MRI scan can be performed. If CT is utilized, a full spiral scan, or a few selected slices, can be obtained through neighboring joints. Typically, a full spiral scan providing full three-dimensional characterization would be obtained in the joint for which therapy is contemplated. If implants, or molds, for surgical instruments are selected or shaped, using this scan, the subchondral bone shape can be accurately determined from the resultant image data.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • [0101] <ul style="list-style-type: none"> ○ Alternatively, however, the articular cartilage can be fully characterized by performing a spiral CT scan of the joint in the presence of intra-articular contrast or by performing an MRI scan using cartilage sensitive pulse sequences. • [0103] <ul style="list-style-type: none"> ○ Alternatively, or in addition to, non-invasive imaging techniques described above, measurements of the size of an area of diseased cartilage or an area of cartilage loss, measurements of cartilage thickness and/or curvature of cartilage or bone can be obtained intraoperatively during arthroscopy or open arthrotomy. Intraoperative measurements can, but need not, involve actual contact with one or more areas of the articular surfaces. • [0288] <ul style="list-style-type: none"> ○ FIG. 23 is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Typically, the first step is to measure the size of the area of the diseased cartilage or cartilage loss 2100, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage 2120, prior to measuring the curvature of the articular surface and/or the subchondral bone 2130. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage 2102. Once an understanding and determination of the nature of the cartilage defect is determined, either a mold can be selected from a library of molds 3132 or a patient specific mold can be generated 2134. In either event, the implantation site is then prepared 2140 and implantation is performed 2142. Any of these steps can be repeated by the optional repeat steps 2101, 2121, 2131, 2133, 2135, 2141.

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 23 <ul style="list-style-type: none"> ○ <pre> graph TD 2100[Measure Size of Area of Diseased Cartilage or Cartilage Loss 2100] --> 2120[Measure Thickness of Adjacent Cartilage 2120] 2120 --> 2130[Measure Curvature of Articular Surface and/or Subchondral Bone 2130] 2130 --> 2132[Select Best Fitting Mold in Library 2132] 2130 --> 2134[Generate Custom Patient Specific Mold 2134] 2132 --> 2140[Prepare Implantation Site 2140] 2134 --> 2140 2140 --> 2142((Perform Implantation 2142)) </pre> <ul style="list-style-type: none"> • [0136] <ul style="list-style-type: none"> ○ Using information on thickness and curvature of the cartilage, a physical model of the surfaces of the articular cartilage and of the underlying bone can be created. This

Claims of US 8,623,026	Invalidity Contentions
	<p>physical model can be representative of a limited area within the joint or it can encompass the entire joint. For example, in the knee joint, the physical model can encompass only the medial or lateral femoral condyle, both femoral condyles and the notch region, the medial tibial plateau, the lateral tibial plateau, the entire tibial plateau, the medial patella, the lateral patella, the entire patella or the entire joint. The location of a diseased area of cartilage can be determined, for example using a 3D coordinate system or a 3D Euclidian distance as described in WO 02/22014.</p> <ul style="list-style-type: none"> • [0046] <ul style="list-style-type: none"> ○ FIG. 2 is a color reproduction of a three-dimensional thickness map of the articular cartilage of the distal femur. Three-dimensional thickness maps can be generated, for example, from ultrasound, CT or MRI data. Dark holes within the substances of the cartilage indicate areas of full thickness cartilage loss. • Figure 2

Claims of US 8,623,026	Invalidity Contentions
	<ul style="list-style-type: none">○ • [0278]<ul style="list-style-type: none">○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties.

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	<ul style="list-style-type: none"> • [0168] <ul style="list-style-type: none"> ○ The balloon can be slowly injected with a self hardening or hardening material such as a polymer and even metals. The material is initially in a fluid or semi-fluid state. The material expands the balloon whereby the shape of the balloon will take substantially the shape of the articular surface(s) and other articular structures. The polymer will subsequently harden inside the balloon thereby substantially taking the shape of the articular cavity and articular surface(s)/structures. The balloon can also be composed of a bio-resorbable material. The balloon can also be removed after the procedure. • [0275] <ul style="list-style-type: none"> ○ In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes can be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.

Claims of US 8,623,026	Invalidity Contentions
	<p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, [0074] ("The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein."); [0253] ("Performing a total knee arthroplasty is a complicated procedure. In replacing the knee with an artificial knee, it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee."); [0274] ("However, it is also possible to make molds that are designed to fit to a bone or portions of a joint after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The mold can account for the shape of the bone or the joint resulting from these procedures."); [0289] ("Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention"); [0294] ("Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface."); [307] ("Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention."); [0316] ("As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>invention.”); [0353] (“The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims equivalents thereof.”).</p>
<p>[52.C] at least a portion of the surface further including an anatomical relief; and</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious at least a portion of the surface further including an anatomical relief, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint. <i>See</i> analysis and material cited for claim 15.B.iii, above.</p> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA’s knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants’ Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants’ Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 15.B.iii, above.</p>
<p>[52.D.i] at least one guide for directing movement of a surgical instrument; and</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious at least one guide for directing movement of a surgical instrument, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint. <i>See</i> analysis and material cited for claim 15.C.i, above.</p>

Claims of US 8,623,026	Invalidity Contentions
	<p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 15.C.i, above.</p>
<p>[52.D.ii] wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis.</p>	<p>Berez discloses (explicitly, implicitly, and inherently) and also renders obvious wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint. <i>See</i> analysis and material cited for claim 15.C.ii, above.</p> <p>Further, to the extent that ConforMIS contends Berez does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Berez and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

Claims of US 8,623,026	Invalidity Contentions
	For example, Berez teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 15.C.ii, above.

Exhibit 3

Invalidity of U.S. Patent No. 9,295,482 in view of U.S. Patent No. 6,510,334 to Luis Schuster & Christoph Schuster

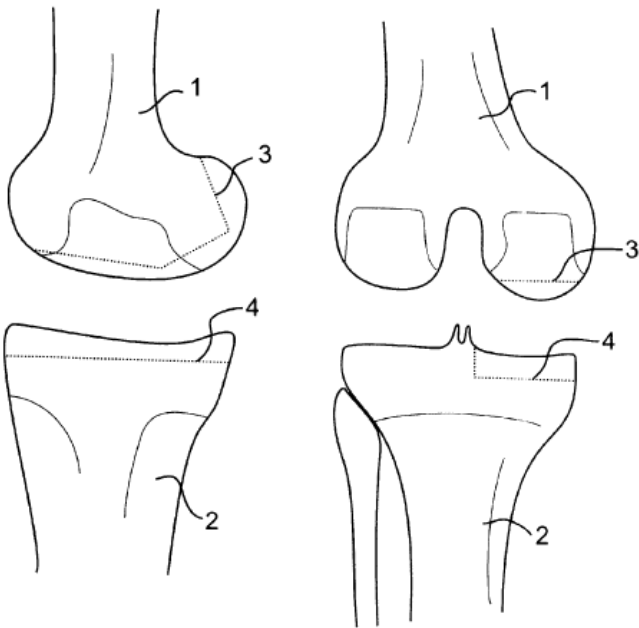
The following chart provides an analysis of the invalidity of claims 1, 17 of U.S. Patent No. 9,295,482 (“the ’482 Patent”) over U.S. Patent No. 6,510,334 to Luis Schuster & Christoph Schuster (“Schuster I”). Schuster I was filed November 14, 2000 and issued January 21, 2003. Schuster I incorporates by reference U.S. Patent No. 4,759,350 to Harold K. Dunn et al., which issued on July 26, 1988. Schuster I also incorporates by reference U.S. Patent No. 5,735,277 to Luis Schuster, which issued April 7, 1998. Schuster I qualifies as prior art to the ’482 Patent under at least 35 U.S.C. § 102 (a), (b), (e) (pre-AIA). Schuster I anticipates and renders obvious each claim of the ’482 Patent, as explained in the chart below and in the contentions. The citations below are not intended to be limiting and are for the purpose of illustrating Defendants’ invalidity theories only. Defendants reserve the right to rely on all parts of Schuster I and disclosures incorporated therein, whether expressly cited below or not.

In addition and in the alternative, Schuster I renders all claims obvious in combination with one or more of the prior art references identified in Defendants’ Invalidity Contentions. It would have been obvious to combine Schuster I with any one or more of these other prior art references, which are analogous art, at least because such combinations: combine prior art elements according to known methods to yield predictable results; are a simple substitution of one known element for another to obtain predictable results; use known techniques to improve similar devices, methods, or products in the same way; apply a known technique to a known device, method, or product ready for improvement to yield predictable results; are obvious to try, including because they choose from a finite number of identified, predictable solutions with a reasonable expectation of success; use a known work in one field of endeavor to prompt variations of it for use in either the same field or a different one based on design incentives or other market forces since the variations are predictable to one of ordinary skill in the art; and contain some teaching, suggestion, or motivation that would have led one of ordinary skill in the art to modify or combine Schuster I to arrive at the claimed invention. Defendants have provided certain exemplary combinations for illustration. However, these combinations are merely exemplary and non-limiting. For avoidance of doubt, Defendants also rely on combinations with the other references described in Exhibit A and in the other claim charts. Additionally, ConforMIS’s disclosures regarding the priority dates of its own patents and patent applications is unclear and deficient. Defendants reserve the right to use any of the asserted patents and the applications cited therein as prior art to other asserted patents.

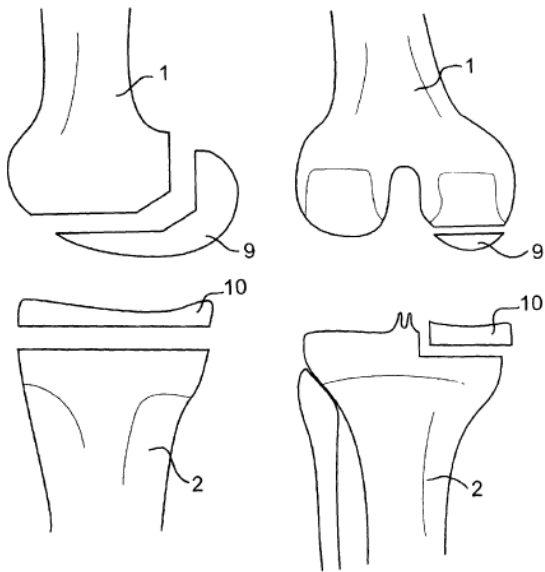
ConforMIS has applied overly broad constructions of various limitations of the asserted claims in its complaint and in its infringement contentions. This claim chart takes into account ConforMIS’s overly broad construction of the claim limitations, including the constructions implicit in its complaint and infringement contentions. Any assertion that a particular limitation is disclosed by a prior art reference or references may be based in whole or in part on ConforMIS’s apparent constructions and is not intended to be, and is not, an admission that such constructions are supportable or proper. Rather, any construction broad enough to allegedly read on any accused method or structure would necessarily read on the prior art, further confirming that the claims are invalid.

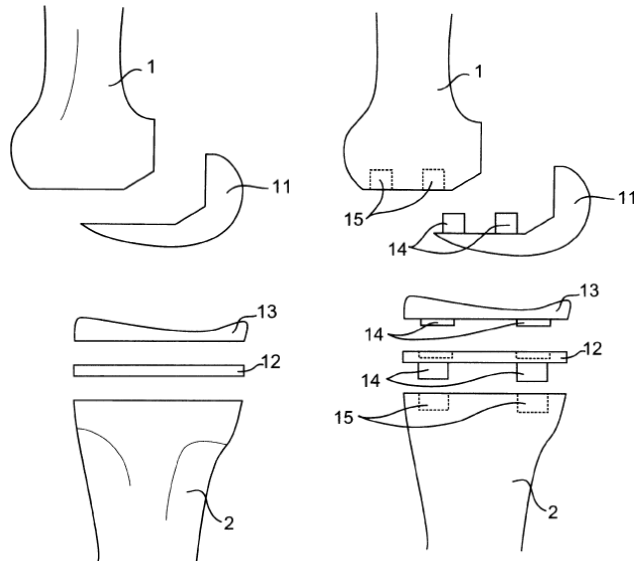
Claims of US 9,295,482	Invalidity Contentions
<p>[1-pre] A joint arthroplasty system for repairing a diseased or damaged joint of a patient[]comprising</p>	<p>To the extent that the preamble is limiting, Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a joint arthroplasty system for repairing a diseased or damaged joint of a patient, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Abstract <ul style="list-style-type: none"> ○ In a method of producing an endoprosthesis as an joint substitute for knee joints three-dimensional femoral and tibial components of the endoprosthesis are prepared in combination with three-dimensional femoral and tibial components of an associated implantation aid on the basis of respective visual patterns that are derived from virtually altering a preoperative tomographic image of a damaged knee joint. • Column 1, Lines 8-13 <ul style="list-style-type: none"> ○ This invention relates to a method of producing an endoprosthesis as a joint substitute for knee joints. The invention further also relates to an operative set for carrying out operations on damaged knee joints utilising an endoprosthesis which is produced in accordance with the method of this invention. • Column 2, Lines 39-53 <ul style="list-style-type: none"> ○ An object of the present invention is therefore to provide a method of producing an endoprosthesis as a joint substitute for knee joints which minimises the error rate in connection with a surgical intervention on a damaged knee joint and which further optimizes the surgical intervention in respect of the possibility to allow a very close adaption at least of the femoral and tibial components of an endoprosthesis to the

Claims of US 9,295,482	Invalidity Contentions
	<p>contours of the bone joints as specifically prepared on respective surfaces during a surgical intervention for snugly fitting thereto the components of the endoprosthesis.</p> <p>A further object of the present invention relates to the provision of an operative set for carrying out operations on damaged knee joints which will allow a practically readymade surgical intervention on a damaged knee joint as accompanied with less pain for the patient.</p> <ul style="list-style-type: none"> • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63 <ul style="list-style-type: none"> ○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoin and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 1 <ul style="list-style-type: none"> ○  • Column 5, Lines 20-23 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 15-39

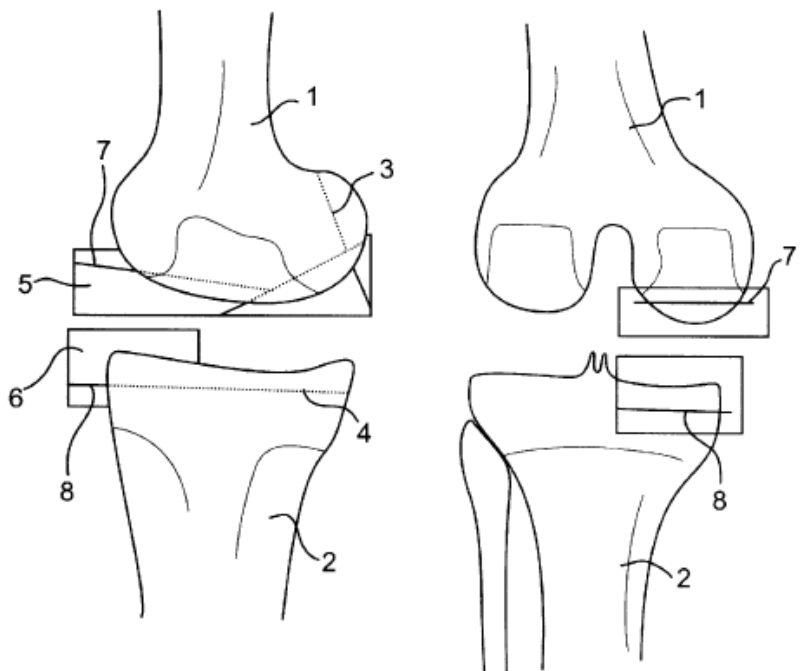
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The altered femoral and tibial components defining therefore respective components of a healthy knee joint are subsequently virtually severed as respectively visual patterns for the endoprosthesis. The severing is carried out on marked severing areas which later serve as thusly predetermined severing areas for severing the associated components of the damaged knee joint from the joint bones during the factual operation of the damaged knee joint. The severing is carried out on the femoral bone of the damaged knee joint preferably with three different severing areas and on the tibia with one or with two different severing areas. By this virtual severing visual patterns are therefore obtained which are directly oriented in respect to the damaged knee joint and thusly allow a preparation of femoral and tibial components of an endoprosthesis which exactly correspond to the femoral and tibia components as altered by the preceding step of virtually altering the preoperative tomographic image of the damaged knee joint. The different severing areas as marked for this virtual severing step could preferably also be supplemented virtually with anchoring means such as, e.g., pegs for the three-dimensional components of the endoprosthesis when later fitted to the resection areas of the joint bones. Such pegs when exemplified would then be intended for being fitted snugly into associated peg holes of the corresponding resection areas of the joint bones. • Column 5, Lines 3-8 <ul style="list-style-type: none"> ○ FIG. 3 illustrates schematically the virtual severing of femoral and tibial components of the damaged knee joint after having been virtually altered on the preoperative tomographic image for approximating the contours of the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint. • Figure 3

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Lines 27-36 <ul style="list-style-type: none"> ○ Numeral 9 and 10 refer to the femoral and tibial components of the damaged knee joint when severed virtually from the preoperative tomographic image of the damaged knee joint after it has been virtually altered for approximating the contours of the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint whereby these femoral and tibial components serve as visual patterns for the preparation of three-dimensional femoral and tibial components of the endoprosthesis. • Column 5, Lines 9-18

Claims of US 9,295,482	Invalidity Contentions
	<p>○ FIG. 4 illustrates schematically the three-dimensional femoral and tibia components of the endoprosthesis as prepared on the basis of their respective visual patterns.</p> <p>FIG. 5 illustrates schematically the femoral and tibial components of the endoprosthesis in accordance with an alternative embodiment and inducing pegs and associated pegs holes for allowing the components to be snugly fitted to the femoral bone and the tibia of the knee joint after its operation by use of the femoral and tibial components of the implantation and.</p> <ul style="list-style-type: none"> • Figures 4 & 5 <ul style="list-style-type: none"> ○  • Column 5, Lines 36-40

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Numerals 11, 12 and 13 refer to the components of the endoprosthesis which may be provided with pegs 14 that will fit snugly into peg holes 15 of the associated resection areas on the femoral bone 1 and of the tibia 2. • Column 3, Lines 40 – Column 4, Line 5 <ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none">• Column 4, Line 64 – Column 5, Line 2<ul style="list-style-type: none">○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint.• Figure 2

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtualty transferred during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 4, Lines 32-41 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative set. • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . <p style="margin-left: 40px;">virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones;</p> • Claim 4 <ul style="list-style-type: none"> ○ The method of claim 1, wherein the tomographic images are prepared by a nuclear spin resonance tomography.

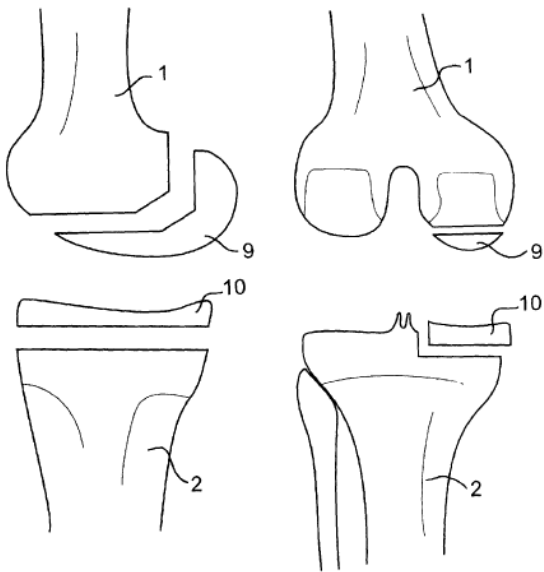
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 4, Lines 20-24 <ul style="list-style-type: none"> ○ The same "Rapid Prototyping" may also be used for the preparation of corresponding STL patterns made, e.g., of epoxy resin and provided with those guiding slots at the marked severing areas which have been virtually transferred during the preceding step. <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>
[1.A] an implant; and	Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious an implant, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.

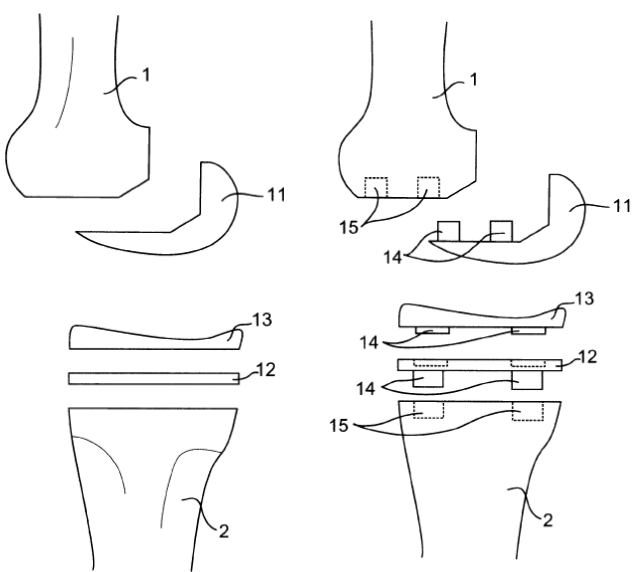
Claims of US 9,295,482	Invalidity Contentions
	<p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Abstract <ul style="list-style-type: none"> ○ In a method of producing an endoprosthesis as an joint substitute for knee joints three-dimensional femoral and tibial components of the endoprosthesis are prepared in combination with three-dimensional femoral and tibial components of an associated implantation aid on the basis of respective visual patterns that are derived from virtually altering a preoperative tomographic image of a damaged knee joint. • Column 1, Lines 8-13 <ul style="list-style-type: none"> ○ This invention relates to a method of producing an endoprosthesis as a joint substitute for knee joints. The invention further also relates to an operative set for carrying out operations on damaged knee joints utilising an endoprosthesis which is produced in accordance with the method of this invention. • Column 2, Lines 39-53 <ul style="list-style-type: none"> ○ An object of the present invention is therefore to provide a method of producing an endoprosthesis as a joint substitute for knee joints which minimises the error rate in connection with a surgical intervention on a damaged knee joint and which further optimizes the surgical intervention in respect of the possibility to allow a very close adaption at least of the femoral and tibial components of an endoprosthesis to the contours of the bone joints as specifically prepared on respective surfaces during a surgical intervention for snugly fitting thereto the components of the endoprosthesis. <p>A further object of the present invention relates to the provision of an operative set for carrying out operations on damaged knee joints which will allow a practically</p>

Claims of US 9,295,482	Invalidity Contentions
	<p>readymade surgical intervention on a damaged knee joint as accompanied with less pain for the patient.</p> <ul style="list-style-type: none"> • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63 <ul style="list-style-type: none"> ○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoin and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint. • Figure 1

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p> <ul style="list-style-type: none"> • Column 5, Lines 20-23 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 15-39 <ul style="list-style-type: none"> ○ The altered femoral and tibial components defining therefore respective components of a healthy knee joint are subsequently virtually severed as respectively visual patterns

Claims of US 9,295,482	Invalidity Contentions
	<p>for the endoprosthesis. The severing is carried out on marked severing areas which later serve as thusly predetermined severing areas for severing the associated components of the damaged knee joint from the joint bones during the factual operation of the damaged knee joint. The severing is carried out on the femoral bone of the damaged knee joint preferably with three different severing areas and on the tibia with one or with two different severing areas. By this virtual severing visual patterns are therefore obtained which are directly oriented in respect to the damaged knee joint and thusly allow a preparation of femoral and tibial components of an endoprosthesis which exactly correspond to the femoral and tibia components as altered by the preceding step of virtually altering the preoperative tomographic image of the damaged knee joint. The different severing areas as marked for this virtual severing step could preferably also be supplemented virtually with anchoring means such as, e.g., pegs for the three-dimensional components of the endoprosthesis when later fitted to the resection areas of the joint bones. Such pegs when exemplified would then be intended for being fitted snugly into associated peg holes of the corresponding resection areas of the joint bones.</p> <ul style="list-style-type: none"> • Column 5, Lines 3-8 <ul style="list-style-type: none"> ○ FIG. 3 illustrates schematically the virtual severing of femoral and tibial components of the damaged knee joint after having been virtually altered on the preoperative tomographic image for approximating the contours of the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint. • Figure 3

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Lines 27-36 <ul style="list-style-type: none"> ○ Numeral 9 and 10 refer to the femoral and tibial components of the damaged knee joint when severed virtually from the preoperative tomographic image of the damaged knee joint after it has been virtually altered for approximating the contours of the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint whereby these femoral and tibial components serve as visual patterns for the preparation of three-dimensional femoral and tibial components of the endoprosthesis. • Column 5, Lines 9-18

Claims of US 9,295,482	Invalidity Contentions
	<p>○ FIG. 4 illustrates schematically the three-dimensional femoral and tibia components of the endoprosthesis as prepared on the basis of their respective visual patterns.</p> <p>FIG. 5 illustrates schematically the femoral and tibial components of the endoprosthesis in accordance with an alternative embodiment and inducing pegs and associated pegs holes for allowing the components to be snugly fitted to the femoral bone and the tibia of the knee joint after its operation by use of the femoral and tibial components of the implantation and.</p> <ul style="list-style-type: none"> • Figures 4 & 5 <ul style="list-style-type: none"> ○  • Column 5, Lines 36-40

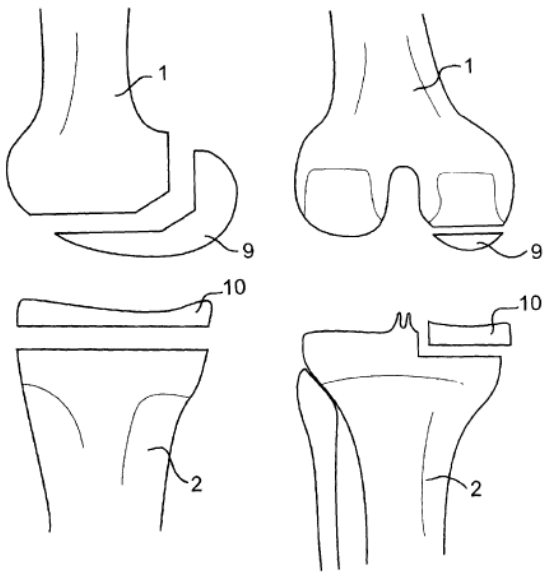
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Numerals 11, 12 and 13 refer to the components of the endoprosthesis which may be provided with pegs 14 that will fit snugly into peg holes 15 of the associated resection areas on the femoral bone 1 and of the tibia 2. • Column 4, Lines 32-50 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative Set. These components may therefore be snugly fitted to the resection areas by means of the anchoring pegs which will be anchored in associated peg holes of the resection areas. When no anchoring means as e.g., such pegs corresponding peg holes are provided the components of the endoprosthesis could then also be put together by any known cementing method which will allow a correct seating of the components of the endoprosthesis prior to a final closing of the knee joint. • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . <p style="margin-left: 40px;">preparing a preoperative tomographic image of the damaged knee joint; virtually altering the preoperative tomographic image for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint;</p>

Claims of US 9,295,482	Invalidity Contentions
	<p>virtually severing the altered femoral and tibial components defining respective components of a healthy knee joint as respectively visual patterns for the endoprosthesis whereby this Severing is carried out on marked severing areas which later serve as thusly predetermined severing areas for severing the associated sociated components of the damaged knee joint from the joint bones during operation of the damaged knee joint;</p> <p>virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones;</p> <p>preparing three-dimensional femoral and tibial components of the endoprosthesis and three-dimensional femoral and tibial components of the associated implantation aid on the basis of their respective visual patterns.</p> <ul style="list-style-type: none"> • Column 4, Lines 6-20 <ul style="list-style-type: none"> ○ The visual patterns of both the femoral and tibial components of the endoprosthesis and the femoral and tibial components of the associated implantation aid are then used for preparing corresponding three-dimensional parts. Such a conversion could be exemplified by means of the so-called “Rapid Prototyping” (incorporated by reference) according to which there are obtained so-called STL patterns which may be used for the preparation of the three-dimensional components as mouldings in a casting process. The tibial component of the endoprosthesis could be produced as a metallic part for

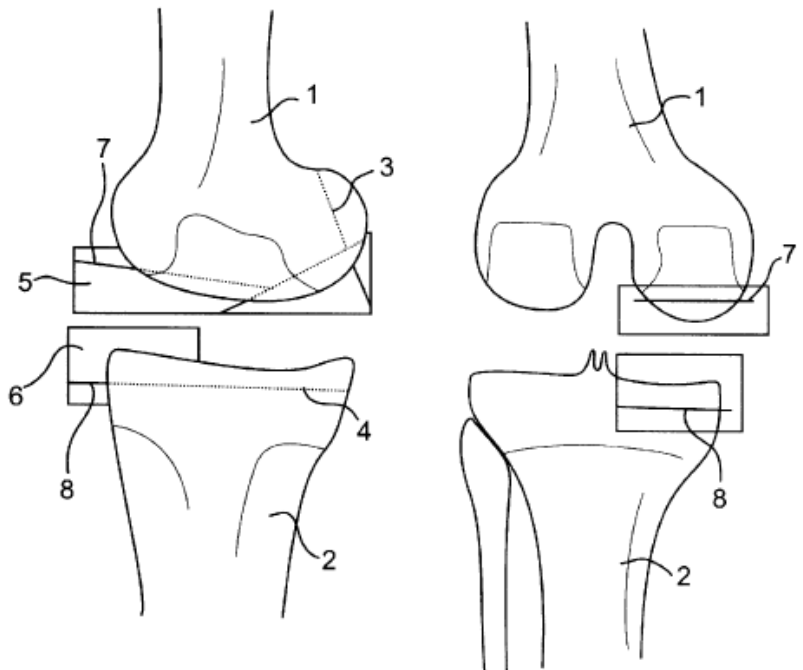
Claims of US 9,295,482	Invalidity Contentions
	<p>being arranged on its associated joint bone and further of a separate plastic part which will receive an arrangement between this metallic part of the tibial component and an also metallic part defining the femoral component of the endoprosthesis.</p> <ul style="list-style-type: none"> • <i>See also</i> Claims 9, 10, 11 <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damaged knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>
[1.B] a patient-specific surgical instrument configured to facilitate the	Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a patient-specific surgical instrument configured to facilitate the placement of the implant into the diseased or damaged

Claims of US 9,295,482	Invalidity Contentions
<p>placement of the implant into the diseased or damaged joint, the instrument comprising:</p>	<p>joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 3, Lines 15-39 <ul style="list-style-type: none"> ○ The altered femoral and tibial components defining therefore respective components of a healthy knee joint are subsequently virtually severed as respectively visual patterns for the endoprosthesis. The severing is carried out on marked severing areas which later serve as thusly predetermined severing areas for severing the associated components of the damaged knee joint from the joint bones during the factual operation of the damaged knee joint. The severing is carried out on the femoral bone of the damaged knee joint preferably with three different severing areas and on the tibia with one or with two different severing areas. By this virtual severing visual patterns are therefore obtained which are directly oriented in respect to the damaged knee joint and thusly allow a preparation of femoral and tibial components of an endoprosthesis which exactly correspond to the femoral and tibia components as altered by the preceding step of virtually altering the preoperative tomographic image of the damaged knee joint. The different severing areas as marked for this virtual severing step could preferably also be supplemented virtually with anchoring means such as, e.g., pegs for

Claims of US 9,295,482	Invalidity Contentions
	<p>the three-dimensional components of the endoprosthesis when later fitted to the resection areas of the joint bones. Such pegs when exemplified would then be intended for being fitted snugly into associated peg holes of the corresponding resection areas of the joint bones.</p> <ul style="list-style-type: none">• Column 5, Lines 3-8<ul style="list-style-type: none">○ FIG. 3 illustrates schematically the virtual severing of femoral and tibial components of the damaged knee joint after having been virtually altered on the preoperative tomographic image for approximating the contours of the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint.• Figure 3

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Lines 27-36 <ul style="list-style-type: none"> ○ Numeral 9 and 10 refer to the femoral and tibial components of the damaged knee joint when severed virtually from the preoperative tomographic image of the damaged knee joint after it has been virtually altered for approximating the contours of the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint whereby these femoral and tibial components serve as visual patterns for the preparation of three-dimensional femoral and tibial components of the endoprosthesis. • Column 3, Lines 40 – Column 4, Line 5

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones. ● Column 4, Line 64 – Column 5, Line 2 ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint.

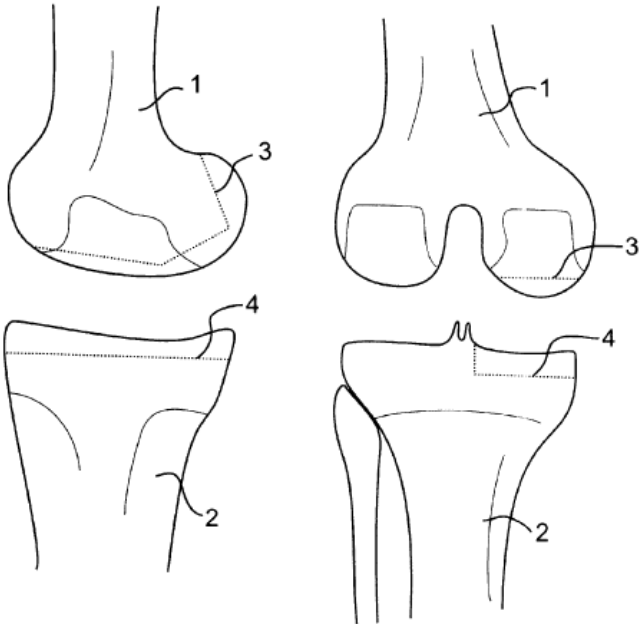
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 2 <ul style="list-style-type: none"> ○  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are

Claims of US 9,295,482	Invalidity Contentions
	<p>virtualty transfered during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.</p> <ul style="list-style-type: none"> • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . <p style="margin-left: 40px;">virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones; . . .</p> <ul style="list-style-type: none"> • Column 4, Lines 32-50 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative Set. These components may therefore be snugly fitted to the resection areas by means of the anchoring pegs which will be anchored in associated peg holes of the resection areas. When no anchoring means as e.g., such pegs corresponding peg holes are provided the components of the

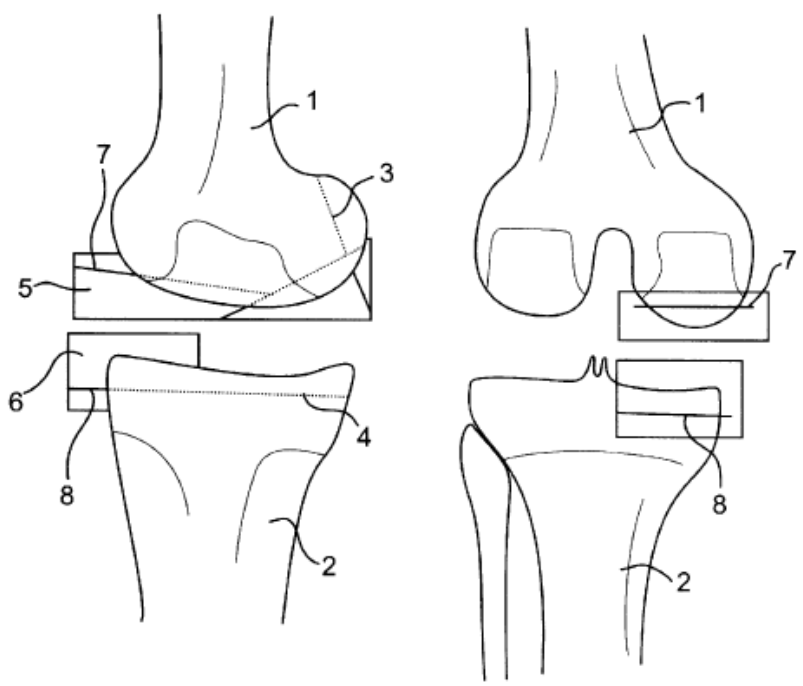
Claims of US 9,295,482	Invalidity Contentions
	<p>endoprosthesis could then also be put together by any known combining method which will allow a correct seating of the components of the endoprosthesis prior to a final closing of the knee joint.</p> <ul style="list-style-type: none"> • Claim 4 <ul style="list-style-type: none"> ○ The method of claim 1, wherein the tomographic images are prepared by a nuclear spin resonance tomography. <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damaged knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>

Claims of US 9,295,482	Invalidity Contentions
<p>[1.B.i] a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint,</p>	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 3, Lines 15-39 <ul style="list-style-type: none"> ○ The altered femoral and tibial components defining therefore respective components of a healthy knee joint are subsequently virtually severed as respectively visual patterns for the endoprosthesis. The severing is carried out on marked severing areas which later serve as thusly predetermined severing areas for severing the associated components of the damaged knee joint from the joint bones during the factual operation of the damaged knee joint. The severing is carried out on the femoral bone of the damaged knee joint preferably with three different severing areas and on the tibia with one or with two different severing areas. By this virtual severing visual patterns are therefore obtained which are directly oriented in respect to the damaged knee joint and thusly allow a preparation of femoral and tibial components of an endoprosthesis which exactly correspond to the femoral and tibia components as altered by the preceding step of virtually altering the preoperative tomographic image of the damaged knee joint. The different severing areas as marked for this virtual severing step could

Claims of US 9,295,482	Invalidity Contentions
	<p>preferably also be supplemented virtually with anchoring means such as, e.g., pegs for the three-dimensional components of the endoprosthesis when later fitted to the resection areas of the joint bones. Such pegs when exemplified would then be intended for being fitted snugly into associated peg holes of the corresponding resection areas of the joint bones.</p> <ul style="list-style-type: none"> • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63 <ul style="list-style-type: none"> ○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoint and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint. • Figure 1

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Lines 20-23 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 40 – Column 4, Line 5 <ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged

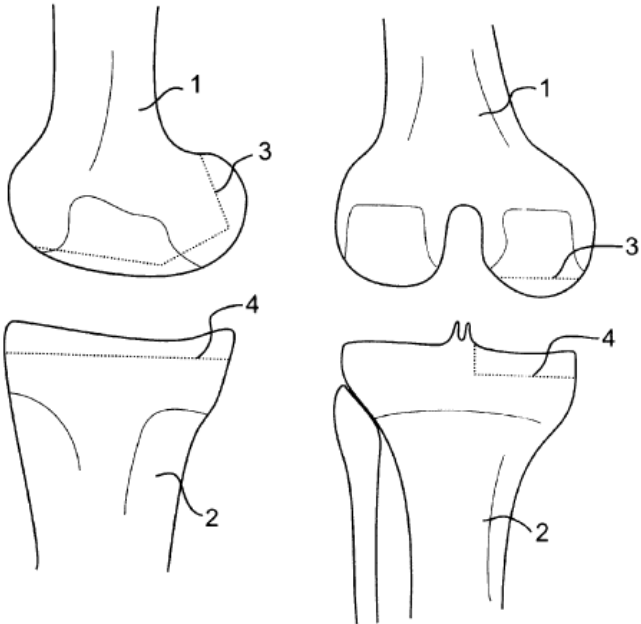
Claims of US 9,295,482	Invalidity Contentions
	<p>knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.</p> <ul style="list-style-type: none"> • Column 4, Line 64 – Column 5, Line 2 <ul style="list-style-type: none"> ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint. • Figure 2

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtualty transfered during a virtual preparation of tomographic images of femoral and

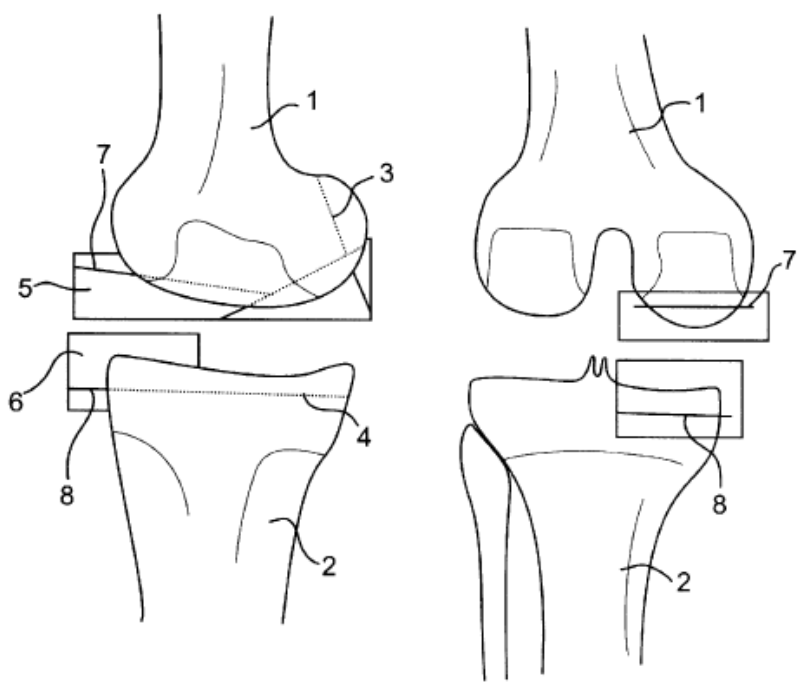
Claims of US 9,295,482	Invalidity Contentions
	<p>tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.</p> <ul style="list-style-type: none"> • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . <p style="margin-left: 40px;">virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones; . . .</p> • Claim 4 <ul style="list-style-type: none"> ○ The method of claim 1, wherein the tomographic images are prepared by a nuclear spin resonance tomography. <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

Claims of US 9,295,482	Invalidity Contentions
	<p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 (“The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues.”); Column 5, Lines 41-47 (“Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.”).</p>
<p>[1.B.ii] the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint,</p>	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Abstract <ul style="list-style-type: none"> ○ In a method of producing an endoprosthesis as an joint substitute for knee joints three-dimensional femoral and tibial components of the endoprosthesis are prepared in combination with three-dimensional femoral and tibial components of an associated implantation aid on the basis of respective visual patterns that are derived from virtually altering a preoperative tomographic image of a damaged knee joint. • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing

Claims of US 9,295,482	Invalidity Contentions
	<p>a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method.</p> <ul style="list-style-type: none"> • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63 <ul style="list-style-type: none"> ○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoin and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint. • Figure 1

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Lines 20-23 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 40 – Column 4, Line 5 <ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged

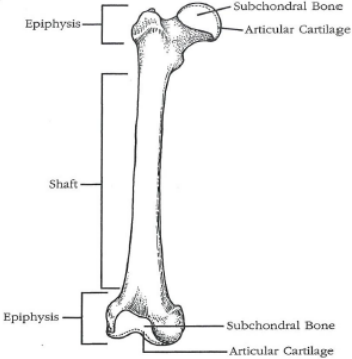
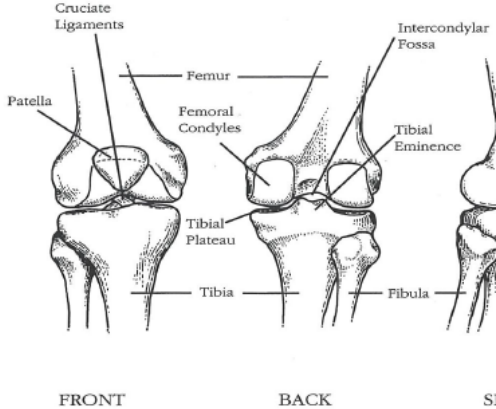
Claims of US 9,295,482	Invalidity Contentions
	<p>knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.</p> <ul style="list-style-type: none"> • Column 4, Line 64 – Column 5, Line 2 <ul style="list-style-type: none"> ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint. • Figure 2

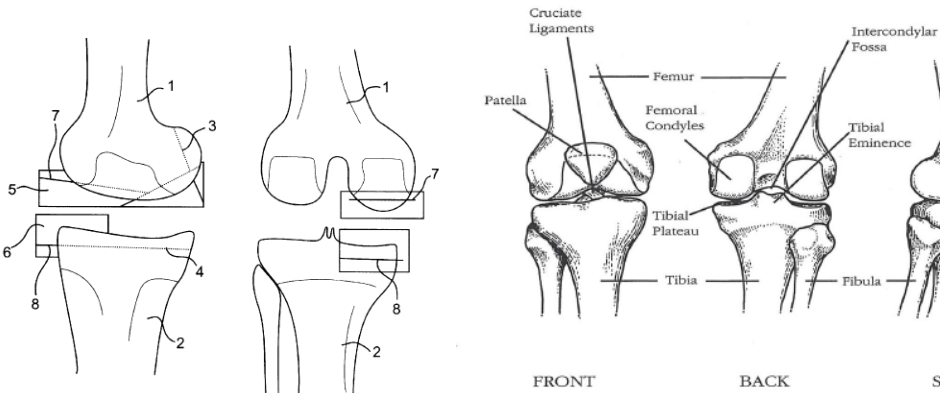
Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtualy transfered during a virtual preparation of tomographic images of femoral and

Claims of US 9,295,482	Invalidity Contentions
	<p>tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.</p> <ul style="list-style-type: none"> • Column 4, Lines 32-41 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative set. • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . <p style="margin-left: 40px;">virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones; . . .</p> • Claim 4


Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The method of claim 1, wherein the tomographic images are prepared by a nuclear spin resonance tomography. <p><u>U.S. 5,735,277 to Luis Schuster (Incorporated by Reference in Schuster I)</u></p> <ul style="list-style-type: none"> • Title <ul style="list-style-type: none"> ○ METHOD OF PRODUCING AN ENDOPROSTHESIS AS A JOINT SUBSTITUTE FOR KNEE-JOINTS • Column 1, Lines 7-11 <ul style="list-style-type: none"> ○ The present invention pertains to a process of producing an endoprosthesis as a joint replacement for knee joints, wherein the production of the prosthesis utilizes information from a surgical intervention on the femur, the tibia, and the patella of a damaged knee joint. • Column 2, Lines 5-17 <ul style="list-style-type: none"> ○ This object is accomplished with a process of producing an endoprosthesis as a joint replacement especially for knee joints by making use of the following steps: <ol style="list-style-type: none"> 1. A preoperative image of the patient's damaged knee joint is prepared. The preparation of such an image may be performed by computed tomography, i.e., a tomographic method, or preferably by nuclear magnetic resonance tomography, because it makes possible an especially sharp definition of the joint contour by representing the cartilaginous tissue and other soft parts of the damaged knee joints, so that correspondingly optimal preconditions are also created for the surgical intervention.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 3, Lines 21-29 <ul style="list-style-type: none"> ○ As a result of the process of producing an endoprosthesis as a joint replacement for knee joints, components are obtained which thus have the contours of the healthy knee joint or lead at most to slightly different joint contours, which are adapted to the current bone-soft tissue conditions and are at the same time correspondingly ideally adapted physiologically, and whose successful implantation will then depend more or less only on the quality of the anchoring of the components. <p>The patient-specific surface including cartilage information is disclosed, both explicitly and inherently in Schuster I, including in Figure 2. For example, compare Fig. 2 from Schuster I with Figs. 3-I and 10-I from THE COLUMBIA PRESBYTERIAN OSTEOARTHRITIS HANDBOOK: THE COMPLETE GUIDE TO THE MOST COMMON FORM OF ARTHRITIS (Ronald P. Gelsamer & Suzanne Loeb, eds. 1997) (“OSTEOARTHRITIS HANDBOOK”) and Figs. 2.8A & 2.8D from SURGERY OF THE KNEE (John N. Insall & W. Norman Scott eds., 3d ed. 2001) (“Insall”).</p> <ul style="list-style-type: none"> • Figs 3-1 and 10-1 from OSTEOARTHRITIS HANDBOOK

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p> <p>FIGURE 3-I: <i>Schematic View of a Long Bone</i></p>  <p>FIGURE 10-I: <i>The Knee: Bony Structure</i></p>  <ul style="list-style-type: none">Figure 1 from Schuster I & Figure 10-I from OSTEOARTHRITIS HANDBOOK

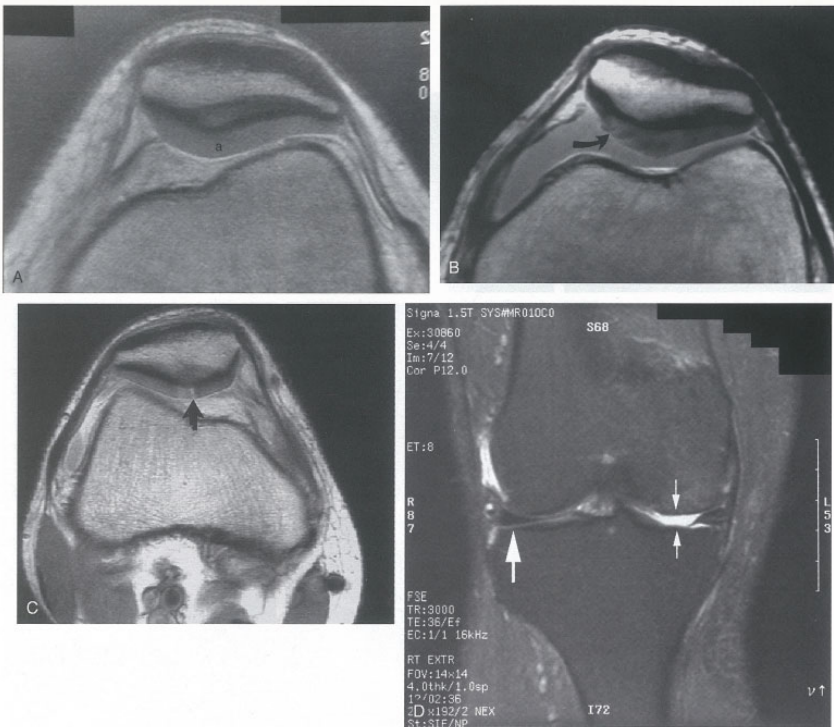
Claims of US 9,295,482	Invalidity Contentions
	<p data-bbox="640 332 661 357">○</p> <p data-bbox="1163 370 1507 389">FIGURE 10-I: <i>The Knee: Bony Structure</i></p>  <p>The figure consists of three anatomical diagrams of a human knee joint. The leftmost diagram is a front view showing the femur (1), patella (7), tibia (2), and fibula (8). The middle diagram is a back view showing the femur (1), tibia (2), and fibula (8). The rightmost diagram is a side view showing the femur (1), patella (7), tibia (2), and fibula (8). Labels include: Cruciate Ligaments, Patella, Femur, Femoral Condyles, Tibial Plateau, Tibia, Fibula, Intercondylar Fossa, and Tibial Eminence. The views are labeled FRONT, BACK, and SIDE.</p> <ul style="list-style-type: none">• Figure 2 from Schuster I and Figures 2.8A & 2.8D from Insall

<p>Claims of US 9,295,482</p>	<p>Invalidity Contentions</p>
	<div data-bbox="638 336 661 355" style="margin-left: 40px;">○</div> <div data-bbox="690 358 1749 915" style="text-align: center;"> </div> <p>Furthermore, nuclear spin resonance tomography (<i>i.e.</i>, MRI), a preferred imaging modality in Schuster I, see Schuster I at 2:59-64, was known in the art to image cartilage. See the following illustrative citations:</p> <p><u>WO2000/035346 to Alexander</u></p> <ul style="list-style-type: none"> • Pages 11-12 <ul style="list-style-type: none"> ○ In Figure 1, the first step 10 represents obtaining an image of the cartilage itself. This is typically achieved using MRI techniques to take an image of the entire knee and then, optionally, manipulating (e.g., "subtracting out" or "extracting") the noncartilage

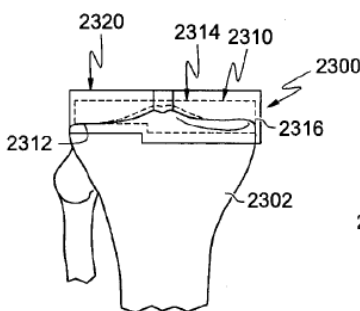
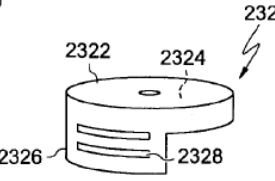
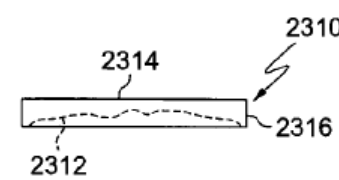
Claims of US 9,295,482	Invalidity Contentions
	<p>images as shown in step 12. Non-cartilage images typically come from bone and fluid. Preferably, the MRI is taken using external markers to provide reference points to the MRI image (step 11).</p> <ul style="list-style-type: none">• Page 14<ul style="list-style-type: none">○ The reason MR imaging techniques are particularly suitable for cartilage is because they can provide accurate assessment of cartilage thickness, demonstrate internal cartilage signal changes, evaluate the subchondral bone for signal abnormalities, and demonstrate morphologic changes of the cartilage surface.• Figure 18C<ul style="list-style-type: none">○

Claims of US 9,295,482	Invalidity Contentions
	<p data-bbox="493 329 1808 394"><u>Klaus Radermacher, <i>Computer-Assisted Surgery Planning and Execution Using Customized Processing Templates in Orthopedics</i> (1999)</u></p> <ul style="list-style-type: none"> <li data-bbox="541 435 709 467">• Page 182 <ul style="list-style-type: none"> <li data-bbox="640 508 1797 979">○ In further work, the exemplary integration and preparation of planning and manufacturing for further clinical applications is to be carried out and clinical testing is to be continued. Furthermore, the possibilities of using alternative methods for acquiring the image and geometry information required for planning and stencil production are to be examined and, if necessary, hybrid methods are to be developed. Thus, depending on the surgical problem, a combination of ultrasound imaging for the acquisition of surface geometry and bi-planar X-ray imaging for the definition of machining geometries is conceivable. Planning and referencing based on cartilaginous joint components, on the other hand, could possibly also be based on MR image data, whereby soft tissue structures in particular, which can be better differentiated in MR image data, such as muscle and tendon attachments, could be included in the planning. For this reason, the merging of CT and MR image data or of CT image data and standardized anatomical and biomechanical models should also be considered. <li data-bbox="541 1027 678 1060">• Page 5 <ul style="list-style-type: none"> <li data-bbox="640 1101 1797 1239">○ In addition, magnetic resonance imaging is used for the early detection of bone marrow necrosis, the assessment of intraosseous tumors, and the visualization and differentiation of muscles, ligaments, tendons, and articular cartilage [Hipp and Gradingner 1988]. <p data-bbox="493 1279 1486 1312"><u>SURGERY OF THE KNEE (John N. Insall & W. Norman Scott eds., 3d ed. 2001)</u></p> <ul style="list-style-type: none"> <li data-bbox="541 1352 695 1385">• Page 22


Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none">○ These changes in the articular cartilage cannot be directly visualized on conventional radiographs but may be seen on magnetic resonance imaging (MRI) studies. However, even MRI is unreliable for detecting early stages of chondromalacia. These may appear as foci or areas of diffuse abnormal signal with a normal surface. Grade III or IV chondromalacia is visible as thinning, irregularity, and fissuring of the cartilage (Fig. 2.16).• Figure 2.16

Claims of US 9,295,482	Invalidity Contentions
	<div><div></div><p>FIGURE 2.16 ➤ A, Axial magnetic resonance imaging (MRI) shows normal articular cartilage (a) on the patella facets. The cartilage has a uniform signal thickness and appearance. B, Axial MRI reveals fissuring and fibrillation of articular cartilage on the medial facet of the patella (arrow). C, Axial MRI with advanced chondromalacia of the patella. The signal irregularity extends to the subchondral bone, and a deep fissure is identified (arrow). D, Coronal MRI demonstrates complete loss of the articular cartilage of the medial compartment (thin arrows). For comparison, the gray band of articular cartilage on the lateral tibial plateau is also identified (thick band).</p></div> <p><u>THE COLUMBIA PRESBYTERIAN OSTEOARTHRITIS HANDBOOK: THE COMPLETE GUIDE TO THE MOST COMMON FORM OF ARTHRITIS (Ronald P. Gelsamer & Suzanne Loeb, eds. 1997)</u></p> <ul style="list-style-type: none">• Page 233

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ Newer imaging techniques produce sharper, three-dimensional images. Computerized axial tomography (CT scan) is particularly good in providing details of bony tissue. Magnetic Resonance Imaging (MRI), which is even more expensive than a CT scan, provides good images of soft tissue. <p><u>US 2004/0236424 to Aaron Berez et al.</u></p> <ul style="list-style-type: none"> • [0083] <ul style="list-style-type: none"> ○ As will be appreciated by those of skill in the art, imaging techniques suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss include the use of x-rays, magnetic resonance imaging (MRI), • [0295] <ul style="list-style-type: none"> ○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone. • Figure 25A, 25B, 25E

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p> <div data-bbox="693 373 1701 714">    </div> <p>FIG. 25A FIG. 25B FIG. 25E</p> <ul style="list-style-type: none"> • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. • [0297] <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis. <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants'</p>

Claims of US 9,295,482	Invalidity Contentions
	<p>Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damaged knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims."). The patient-specific surface in Schuster I is shown on cartilage (see Schuster I at Fig. 2). It was known in the art that MRI (<i>i.e.</i>, nuclear spin resonance tomography, a preferred imaging technique disclosed in Schuster I (see Schuster I at 2:59-64)), can image cartilage and that cartilage is present on the joints of patients undergoing TKA. Therefore, it would have been obvious to a POSITA to at least try including the cartilage information derived from image data in the patient-specific surface, at least under Conformis's implicit construction. See the following illustrative citations:</p> <p><u>WO2000/035346 to Alexander</u></p> <ul style="list-style-type: none"> • Pages 11-12 <ul style="list-style-type: none"> ○ In Figure 1, the first step 10 represents obtaining an image of the cartilage itself. This is typically achieved using MRI techniques to take an image of the entire knee and then, optionally, manipulating (e.g., "subtracting out" or "extracting") the noncartilage images as shown in step 12. Non-cartilage images typically come from bone and fluid.

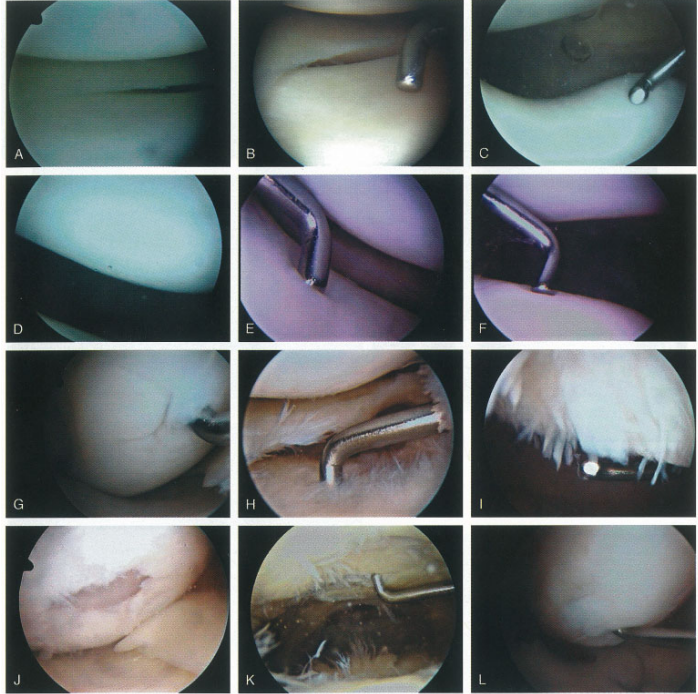
Claims of US 9,295,482	Invalidity Contentions
	<p>Preferably, the MRI is taken using external markers to provide reference points to the MRI image (step 11).</p> <ul style="list-style-type: none"> • Page 14 <ul style="list-style-type: none"> ○ The reason MR imaging techniques are particularly suitable for cartilage is because they can provide accurate assessment of cartilage thickness, demonstrate internal cartilage signal changes, evaluate the subchondral bone for signal abnormalities, and demonstrate morphologic changes of the cartilage surface. • Figure 18C <ul style="list-style-type: none"> ○ <div style="text-align: center;">  <p>FIG. 18C</p> </div> <p><u>Klaus Radermacher, <i>Computer-Assisted Surgery Planning and Execution Using Customized Processing Templates in Orthopedics</i> (1999)</u></p>

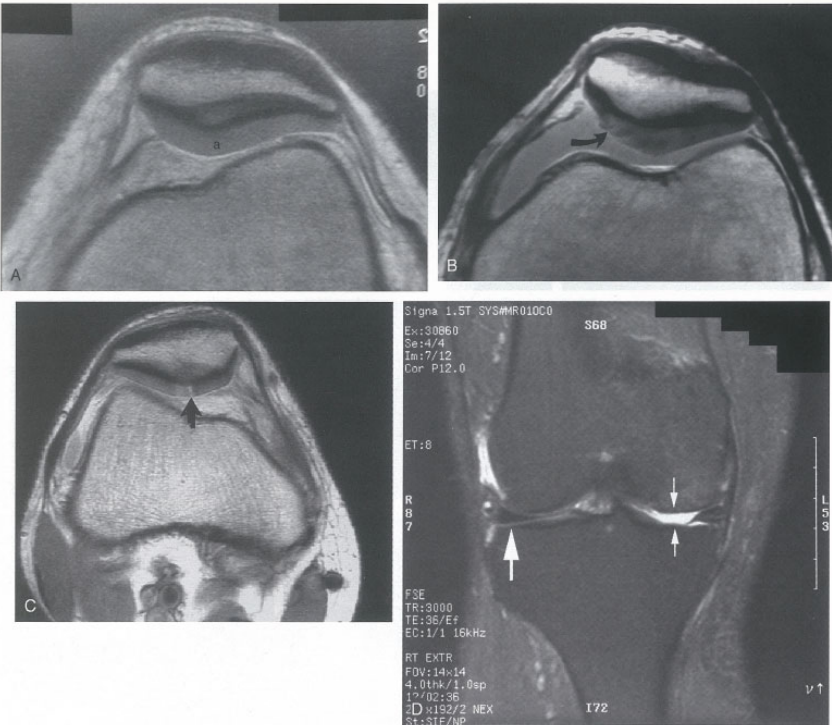
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Page 182 <ul style="list-style-type: none"> ○ Planning and referencing based on cartilaginous joint components, on the other hand, could possibly also be based on MR image data, whereby soft tissue structures in particular, which can be better differentiated in MR image data, such as muscle and tendon attachments, could be included in the planning. For this reason, the merging of CT and MR image data or of CT image data and standardized anatomical and biomechanical models should also be considered. • Page 5 <ul style="list-style-type: none"> ○ In addition, magnetic resonance imaging is used for the early detection of bone marrow necrosis, the assessment of intraosseous tumors, and the visualization and differentiation of muscles, ligaments, tendons, and articular cartilage [Hipp and Grading 1988]. <p><u>Ronald J. Allen et al., ARTHRITIS OF THE HIP & KNEE: THE ACTIVE PERSON'S GUIDE TO TAKING CHARGE (1998)</u></p> <ul style="list-style-type: none"> • Figure 2-2

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p> <p>FIGURE 2-2 <i>Stages of Osteoarthritis of the Knee</i></p> <p>A. Stage I: mild osteoarthritis</p> <p>B. Stage II: moderate osteoarthritis</p>

Claims of US 9,295,482	Invalidity Contentions
	<div data-bbox="688 321 1402 1071"> </div> <div data-bbox="1436 321 1633 539"> <p>FIGURE 2-2</p> <p><i>C. Stage III: moderately severe osteoarthritis</i></p> <p><i>D. Stage IV: severe osteoarthritis</i></p> </div> <div data-bbox="541 1117 1801 1370"> <ul style="list-style-type: none"> • Page 63 <ul style="list-style-type: none"> ○ Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful. </div>

Claims of US 9,295,482	Invalidity Contentions
	<p><u>SURGERY OF THE KNEE (John N. Insall & W. Norman Scott eds., 3d ed. 2001)</u></p> <ul style="list-style-type: none"> • Page 22 <ul style="list-style-type: none"> ○ Examination of gross specimens or arthroscopic visualization reveals normal cartilage to be a white, smooth, and firm material. Articular cartilage damage or degeneration, termed chondromalacia, can be quite readily identified (Fig. 2.14). These characteristic changes seen during arthroscopic examination have been classified by Outerbridge⁶⁴: grade 0 is normal, white-appearing cartilage; grade I is swelling or softening of an intact cartilage surface; grade II is represented by fissuring and fibrillation over a small area (<0.3 inch); grade III is the same pathological changes over a larger area (>0.5 inch); grade IV changes represent erosion to the subchondral bone and are indistinguishable from osteoarthritis. Chondral flap tears caused by delamination of the articular cartilage may also be encountered (Fig. 2.15). • Figure 2.15

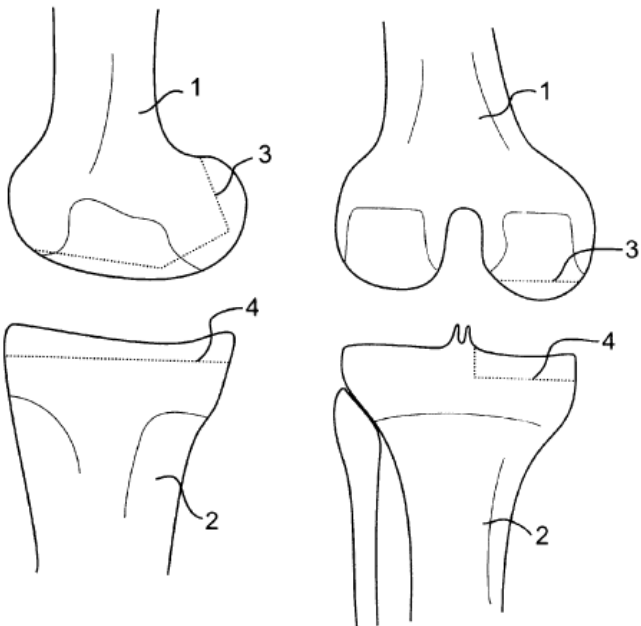
Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <p>FIGURE 2.15 ➤ Arthroscopic views of articular cartilage. Normal white, smooth articular cartilage (Outerbridge grade 0) in the medial (A), lateral (B), and patellofemoral compartments (C and D). Softening of the articular surface of the lateral tibial plateau (E) and patellofemoral articulation (F) with indentation at the probe tip (Outerbridge grade 1) is noted. (G) A small fissure and fibrillation of the medial femoral condyle (Outerbridge grade 2). Extensive fibrillation of the articular cartilage involving the tibial plateau (H) and patella (I) (Outerbridge grade 3). Erosion of articular cartilage to subchondral bone involving the medial femoral condyle (J) and patella (K) (Outerbridge grade 4). Arthroscopic view of a chondral flap tear (L); the probe tip is deep to a flap of delaminated articular cartilage on the medial femoral condyle.</p> <ul style="list-style-type: none"> • Page 22 <ul style="list-style-type: none"> ○ These changes in the articular cartilage cannot be directly visualized on conventional radiographs but may be seen on magnetic resonance imaging (MRI) studies. However, even MRI is unreliable for detecting early stages of chondromalacia. These may appear as foci or areas of diffuse abnormal signal with a normal surface. Grade III or IV

Claims of US 9,295,482	Invalidity Contentions
	<p>chondromalacia is visible as thinning, irregularity, and fissuring of the cartilage (Fig. 2.16).</p> <ul style="list-style-type: none"> Figure 2.16 <ul style="list-style-type: none">  <p>FIGURE 2.16 > A, Axial magnetic resonance imaging (MRI) shows normal articular cartilage (a) on the patella facets. The cartilage has a uniform signal thickness and appearance. B, Axial MRI reveals fissuring and fibrillation of articular cartilage on the medial facet of the patella (arrow). C, Axial MRI with advanced chondromalacia of the patella. The signal irregularity extends to the subchondral bone, and a deep fissure is identified (arrow). D, Coronal MRI demonstrates complete loss of the articular cartilage of the medial compartment (thin arrows). For comparison, the gray band of articular cartilage on the lateral tibial plateau is also identified (thick band).</p>

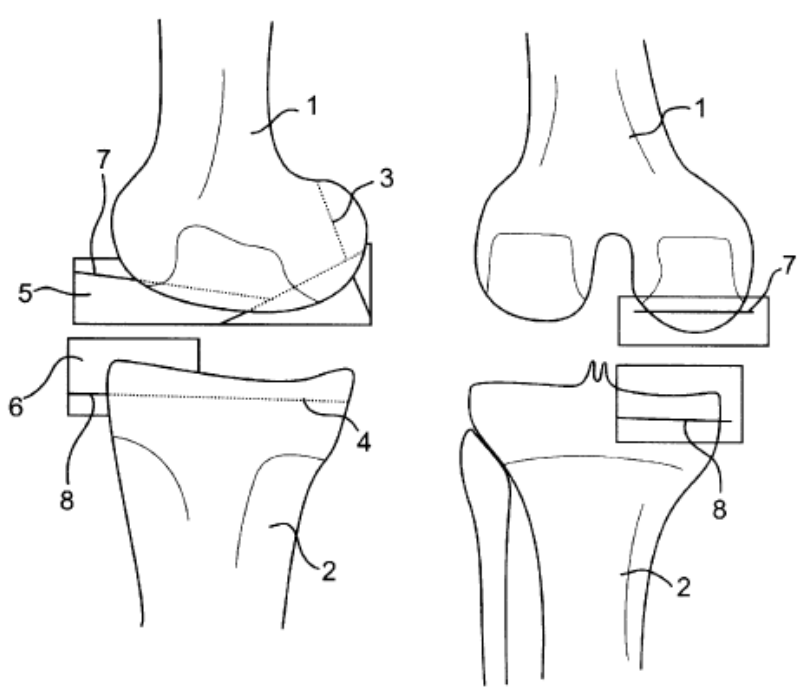
Claims of US 9,295,482	Invalidity Contentions
	<p data-bbox="495 329 1755 394"><u>THE COLUMBIA PRESBYTERIAN OSTEOARTHRITIS HANDBOOK: THE COMPLETE GUIDE TO THE MOST COMMON FORM OF ARTHRITIS (Ronald P. Gelsamer & Suzanne Loeb, eds. 1997)</u></p> <ul style="list-style-type: none"> <li data-bbox="546 440 709 472">• Page 233 <ul style="list-style-type: none"> <li data-bbox="642 516 1785 654">○ Newer imaging techniques produce sharper, three-dimensional images. Computerized axial tomography (CT scan) is particularly good in providing details of bony tissue. Magnetic Resonance Imaging (MRI), which is even more expensive than a CT scan, provides good images of soft tissue. <p data-bbox="495 695 1003 727"><u>US 2004/0236424 to Aaron Berez et al.</u></p> <ul style="list-style-type: none"> <li data-bbox="546 773 676 805">• [0083] <ul style="list-style-type: none"> <li data-bbox="642 849 1797 987">○ As will be appreciated by those of skill in the art, imaging techniques suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss include the use of x-rays, magnetic resonance imaging (MRI), <li data-bbox="546 1032 676 1065">• [0295] <ul style="list-style-type: none"> <li data-bbox="642 1109 1797 1425">○ Turning now to FIG. 25, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. 25A illustrates the tibial cutting block 2300 in conjunction with a tibia 2302 that has not been resected. In this depiction, the cutting block 2300 consists of at least two pieces. The first piece is a patient specific interior piece 2310 or mold that is designed on its inferior surface 2312 to mate, or substantially mate, with the existing geography of the patient's tibia 2302. The superior surface 2314 and side surfaces 2316 of the first piece 2310 are configured to mate within the interior of an exterior piece 2320. The reusable exterior piece 2320 fits over the interior piece 2310. The system can be configured to hold the mold onto the bone.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 25A, 25B, 25E <ul style="list-style-type: none"> ○ <div data-bbox="690 488 1705 833" data-label="Image"> <p>FIG. 25A</p> <p>FIG. 25B</p> <p>FIG. 25E</p> </div> • [0298] <ul style="list-style-type: none"> ○ The interior piece 2310 is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. • [0297] <ul style="list-style-type: none"> ○ The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece 2320 such that it can achieve a cut that is perpendicular to the mechanical axis.
[1.B.iii] wherein the corresponding portion of the diseased or damaged	Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious wherein the corresponding portion of the diseased or damaged joint includes an osteophyte, wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned

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<p>joint includes an osteophyte, wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint;</p>	<p>with the corresponding portion of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Abstract <ul style="list-style-type: none"> ○ In a method of producing an endoprosthesis as an joint substitute for knee joints three-dimensional femoral and tibial components of the endoprosthesis are prepared in combination with three-dimensional femoral and tibial components of an associated implantation aid on the basis of respective visual patterns that are derived from virtually altering a preoperative tomographic image of a damaged knee joint. • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none">○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoin and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint.• Figure 1<ul style="list-style-type: none">○• Column 5, Lines 20-23

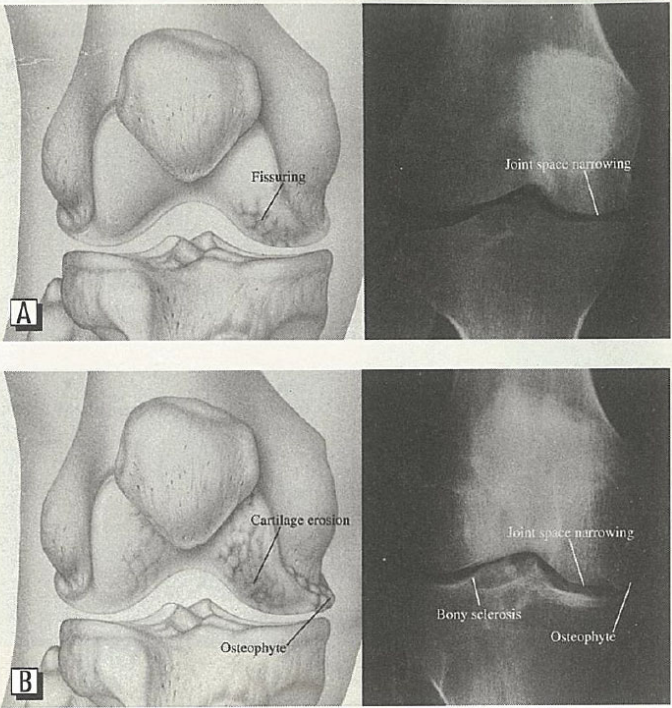
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 40 – Column 4, Line 5 ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 4, Line 64 – Column 5, Line 2 <ul style="list-style-type: none"> ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint. • Figure 2 <ul style="list-style-type: none"> ○ 

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtually transferred during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid. • Column 4, Lines 32-41 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative set. • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid

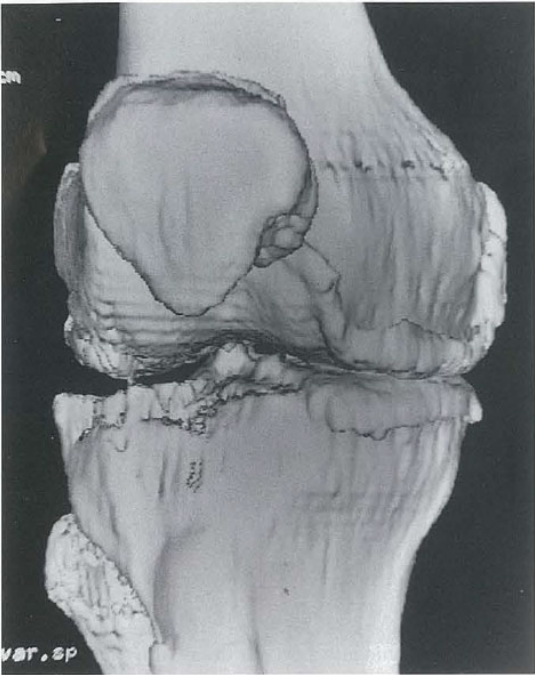
Claims of US 9,295,482	Invalidity Contentions
	<p>are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones; . . .</p> <ul style="list-style-type: none"> • Claim 4 <ul style="list-style-type: none"> ○ The method of claim 1, wherein the tomographic images are prepared by a nuclear spin resonance tomography. <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims."). It was known in the art that osteophytes form in the joint in the locations engaged</p>

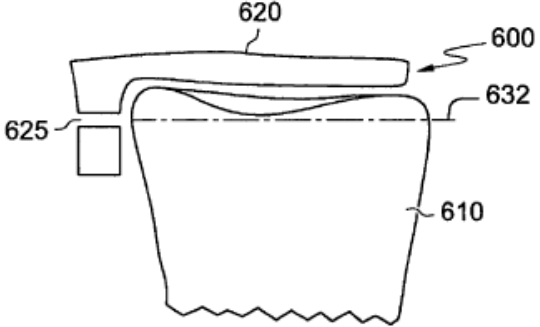
Claims of US 9,295,482	Invalidity Contentions
	<p>by the implementation aids in Schuster I in patients that undergo total knee arthroplasty, and references in the same field taught taking osteophytes into account in designing a patient-specific guide. Thus, a POSITA was motivated to at least try incorporating a patient-specific surface that references an osteophyte, at least under Conformis's implicit construction. See, for example, the following illustrative citations:</p> <p><u>Ronald J. Allen et al., ARTHRITIS OF THE HIP & KNEE: THE ACTIVE PERSON'S GUIDE TO TAKING CHARGE (1998)</u></p> <ul style="list-style-type: none">• Figure 2-2

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p> <p>FIGURE 2-2 <i>Stages of Osteoarthritis of the Knee</i></p> <p>A. Stage I: mild osteoarthritis</p> <p>B. Stage II: moderate osteoarthritis</p> 

Claims of US 9,295,482	Invalidity Contentions
	<div data-bbox="688 321 1407 1079"> </div> <div data-bbox="1444 321 1642 539"> <p>FIGURE 2-2</p> <p><i>C. Stage III: moderately severe osteoarthritis</i></p> <p><i>D. Stage IV: severe osteoarthritis</i></p> </div> <ul style="list-style-type: none"> • Pages 14-15 <ul style="list-style-type: none"> ○ Arthritis creates abnormalities within the structure of the joint. These abnormalities can cause the soft tissue that lines the joint (the synovium) to become inflamed, or they can cause the firm, smooth, shiny surface of the joint (the articular cartilage) to become thin and irregular. The bone under the cartilage may become very dense and stiff. Outgrowths, called osteophytes or spurs, may appear at the edge of the articular

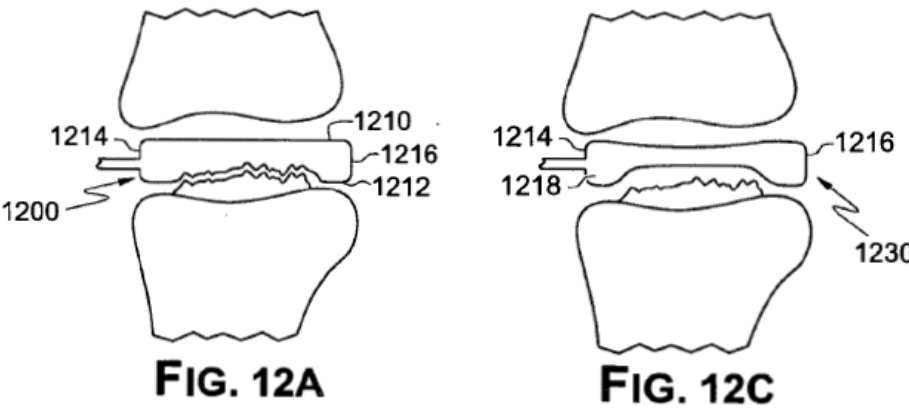
Claims of US 9,295,482	Invalidity Contentions
	<p>cartilage. These abnormalities within the joint cause weakness of the muscles and surrounding ligaments, joint instability, and pain.</p> <ul style="list-style-type: none"> • Page 63 <ul style="list-style-type: none"> ○ Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful. <p><u>SURGICAL TECHNIQUES IN TOTAL KNEE ARTHROPLASTY (Giles R. Scuderi & Alfred J. Tria, Jr. eds. 2002)</u></p> <ul style="list-style-type: none"> • Page 12 <ul style="list-style-type: none"> ○ Degenerative joint disease (DJD) of the knee is the most common condition necessitating total knee arthroplasty. Radiographic findings of DJD are usually clearly evident at the time of presentation and include cartilage loss (joint-space narrowing), subchondral sclerosis and cyst formation, and osteophyte formation² (Fig. 2.11). • Figure 2.14

Claims of US 9,295,482	Invalidity Contentions
	<div>○</div> <div></div> <div><p>Figure 2.14. DJD—3-Dimensional CT: 3-Dimensional reformat image of the knee shows advanced medial compartment disease, with a ridge of osteophytes at the margins of the tibial plateau and femoral condyle.</p></div> <div><p><u>US 2004/0236424 to Berez et al.</u></p><ul style="list-style-type: none">• [0293]<ul style="list-style-type: none">○ FIG. 24A depicts, in cross-section, an example of a mold 600 for use on the tibial surface having an upper surface 620. The mold 600 contains an aperture 625 through</div>

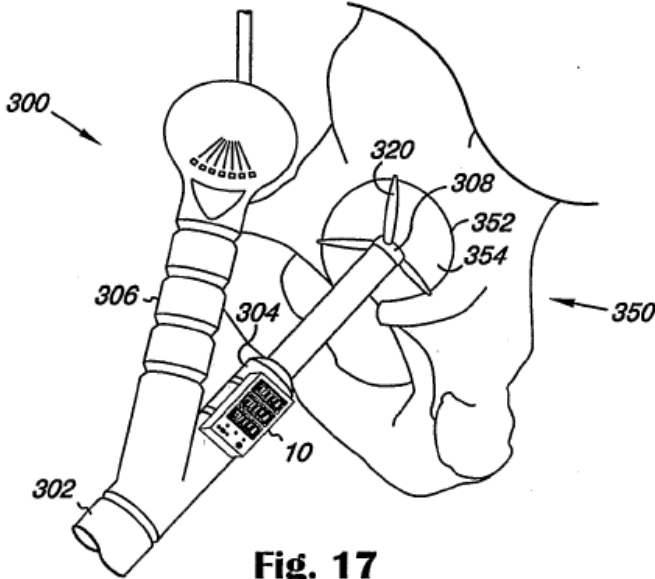
Claims of US 9,295,482	Invalidity Contentions
	<p>which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone 610 as illustrated in FIGS. 21B-D. Dotted lines 632 illustrate where the cut corresponding to the aperture will be made in bone.</p> <ul style="list-style-type: none"> Figure 24A <ul style="list-style-type: none">  Figure 24B

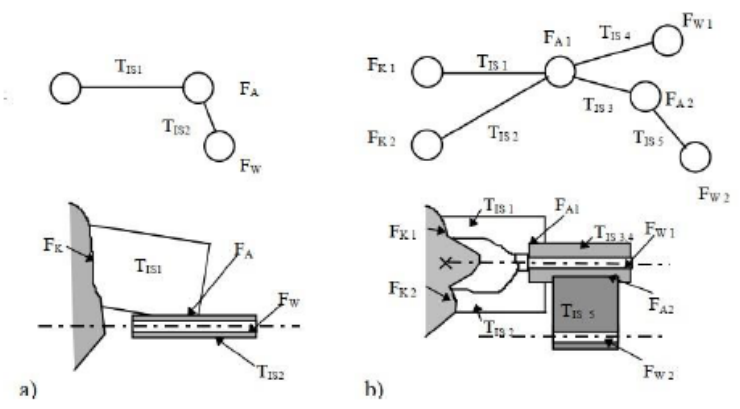
Claims of US 9,295,482	Invalidity Contentions
	<p data-bbox="640 337 661 357">○</p> <div data-bbox="693 370 1108 711"> </div> <p data-bbox="850 727 987 763">FIG. 24B</p> <ul style="list-style-type: none"> <li data-bbox="541 816 1806 1177"> <p>• [0294]</p> <ul style="list-style-type: none"> <li data-bbox="640 889 1806 1177">○ FIG. 24B depicts, a mold 608 suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures 605 enable cuts 606 to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. 21E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface. <li data-bbox="541 1222 1806 1396"> <p>• [0292]</p> <ul style="list-style-type: none"> <li data-bbox="640 1295 1806 1396">○ An anatomically correct tool can be constructed by a number of methods and can be made of any material, preferably a translucent material such as plastic, Lucite, silastic, SLA or the like, and typically is a block-like shape prior to molding.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • [0278] <ul style="list-style-type: none"> ○ Furthermore, re-useable tools (e.g., molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface). In other embodiments, the molds may be made using balloons. The balloons can optionally be filled with a hardening material. A surface can be created or can be incorporated in the balloon that allows for placement of a surgical cut guide, reaming guide, drill guide or placement of other surgical tools. The balloon or other deformable material can be shaped intraoperatively to conform to at least one articular surface. Other surfaces can be shaped in order to be parallel or perpendicular to anatomic or biomechanical axes. The anatomic or biomechanical axes can be found using an intraoperative imaging test or surgical tools commonly used for this purpose in hip, knee or other arthroplasties. • [0179] <ul style="list-style-type: none"> ○ The results of using inflation devices, or balloons, with differing wall thicknesses or pressure tolerances is shown in FIGS. 12A-F. As shown in FIG. 12A the balloon 1200 has an upper surface 1210 and a lower surface 1212 along with a proximal end 1214 and a distal end 1216. The relative pressure tolerance of the balloon or inflation device 1200 is lower on the lower surface 1212 than the upper surface 1210. As a result, the upper surface of the balloon 1210 has a relatively flat configuration relative to its corresponding joint surface while the lower surface 1212 has a relatively conforming shape relative to its corresponding joint surface. • [0181]

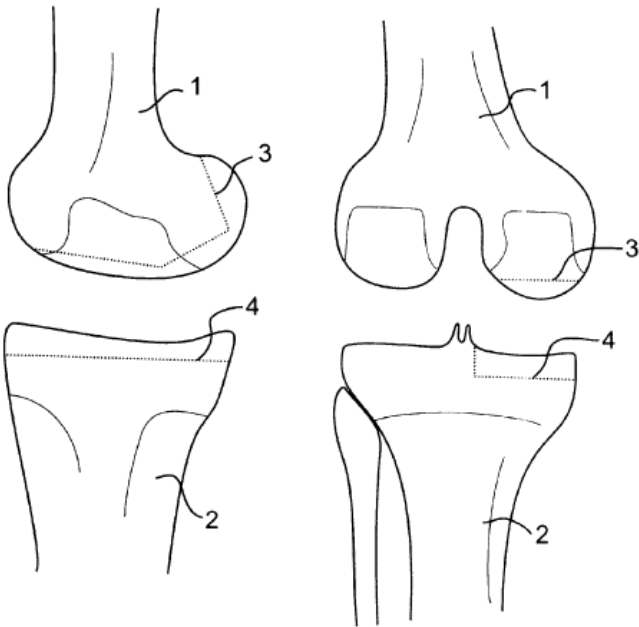
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ FIG. 12C illustrates a balloon 1230 having a low inflation pressure at its proximal 1214 and distal 1216 ends, with a higher inflation pressure at a central region 1218. The result of this configuration is that when the balloon is inflated, the proximal and distal ends inflate to a greater profile (e.g., height) than the central region. The inflation pressure of the central region, although higher than the proximal and distal ends, can be set such that the central region has a relatively flat configuration relative to the corresponding joint surfaces, as shown, or can be configured to achieve the result shown in FIG. 12A. • Figures 12A & 12C <ul style="list-style-type: none"> ○ <div style="text-align: center;">  </div> <ul style="list-style-type: none"> • [0182] <ul style="list-style-type: none"> ○ As will be appreciated by those of skill in the art, any of these balloons can be configured to have varying properties resulting in portions of the wall being less rigid than other portions, within the same balloon, e.g. a rigid wall with high inflation

Claims of US 9,295,482	Invalidity Contentions
	<p>pressures in the periphery and a less rigid wall with intermediate or low inflation pressures in the center. Where there is more than one thickness to the balloon, it could, for example, have less stiffness anteriorly; greater stiffness centrally, and less stiffness posteriorly. The wall thickness variability will enable the device to accommodate shape formation. Central thickness will help prevent the device from fully conforming to the irregular surface of the joint, which may be important where there are irregularities to the joint surface, such as bone spurs. Alternatively, if the central portion is of less stiffness than the anterior and posterior sections, the device would be configured to conform more closely to the shape of the joint surface, including any irregularities. The closer the device conforms to the joint shape, the more the device seats within the joint.</p> <p><u>WO 2004/112610 A2 to Stone et al.</u></p> <ul style="list-style-type: none"> • Paragraph [078] <p>As shown, the alignment guide 308 includes a body portion 318 and wings or arms 320a, 320b, and 320c, which are disposed generally in the same plane. The body portion 318 includes internal threads 316 for mating with the support shaft 304. In one embodiment, the arms 320 secured at points 320 degrees apart around the circumference of the body portion 318 by pivots 324a, 324b, and 324c. The pivots 324 allow for slight in-plane rotation of the arms 320 where necessary, for example to avoid contact with an anatomical aberration as the lip of the acetabulum.</p> • Paragraph [083] <ul style="list-style-type: none"> ○ According to one embodiment, as described above, the arms 320 are adjusted in length by the surgeon using a telescoping action. In another embodiment, the surgeon may need to pivot the arms 320 to avoid an osteophyte or other surface aberration on the rim 352 of the acetabulum 354.

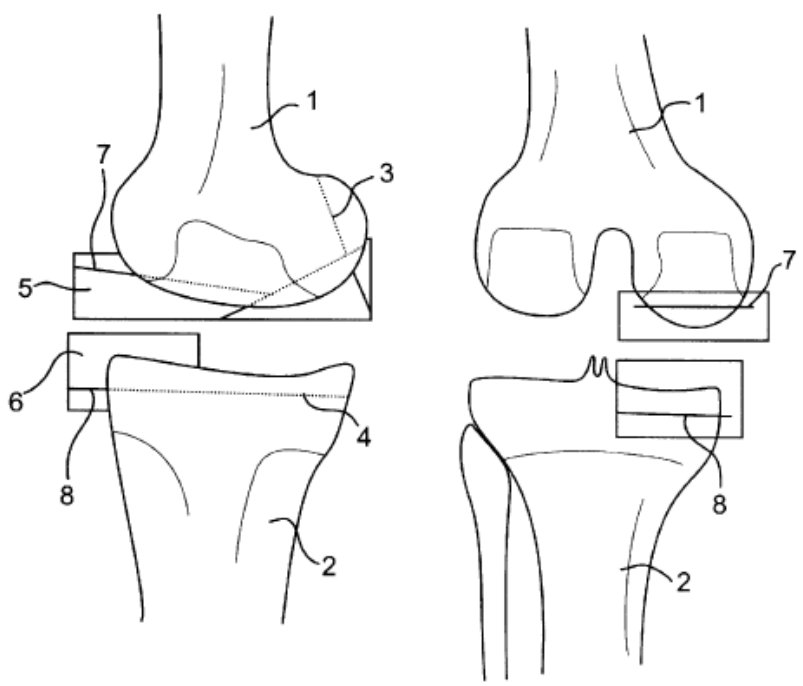
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 17 <ul style="list-style-type: none"> ○  • Paragraph [091] <ul style="list-style-type: none"> ○ The guide 510 is placed on the rim of the glenoid, such that the upper arm is placed at the most superior position of the rim, and the anterior and posterior arms are generally aligned in the center of the superior/posterior glenoid (block 558). Again, the arms may be adjusted to avoid significant osteophytes. • Paragraph [092]

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	<p>○ In yet another embodiment, the device 10 is used by a surgeon to facilitate TKA.</p> <p><u>Klaus Radermacher, <i>Computer-Assisted Surgery Planning and Execution Using Customized Processing Templates in Orthopedics</i> (1999)</u></p> <ul style="list-style-type: none"> Figure 4-24 <ul style="list-style-type: none"> ○  <p><i>Figure 4-24: Examples of different connection structures of customized templates (cf. [Koller 1994], p. 60): a) simple customized template with one contact, alignment and tool guide surface each and template element as connection structure; b) template with several contact, alignment and tool guide surfaces; the standardized partial elements $T_{IS\ 3,4,5}$ reproduce an intrinsic processing geometry (for example, implant-specific), the functional surfaces F_{A2}, F_{W1} and F_{W2} are in this case generally not individually adapted. Individually adapted functional surfaces are F_{K1} and F_{K2} and, if required such as for alignment and positioning, F_{A1}. The shape of T_{IS1} and T_{IS2} can be standardized or adapted to individual anatomical conditions according to requirements.</i></p> <ul style="list-style-type: none"> Page 90

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ The general technical structure of customized templates can thus be composed of the following elements: <ul style="list-style-type: none"> - Individually adapted contact surface(s) F_{Ki}, - Individually adapted or standardized adapter surfaces (F_{Ai}) for aligning the tool guides, in relation to the reference - Individual, but generally standardized tool guidance surfaces F_{Wi}, as well as a connection structure consisting of one or more individually adapted and/or standardized template partial elements TIS_i (Figure 4-24).
[1.B.iv] a guide sized and shaped to accommodate a surgical tool,	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a guide sized and shaped to accommodate a surgical tool, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 4, Lines 60-63 <ul style="list-style-type: none"> ○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoin and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint. • Figure 1

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Lines 20-23 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 40 – Column 4, Line 5 <ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged

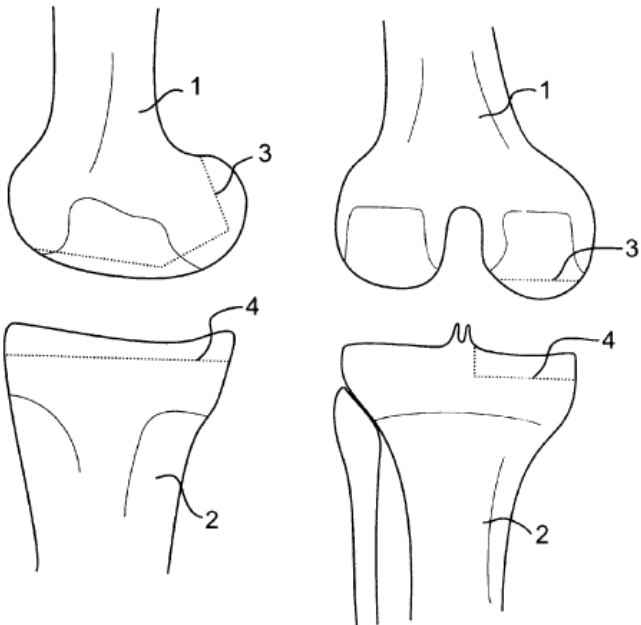
Claims of US 9,295,482	Invalidity Contentions
	<p>knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.</p> <ul style="list-style-type: none"> • Column 4, Line 64 – Column 5, Line 2 <ul style="list-style-type: none"> ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint. • Figure 2

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtualy transfered during a virtual preparation of tomographic images of femoral and

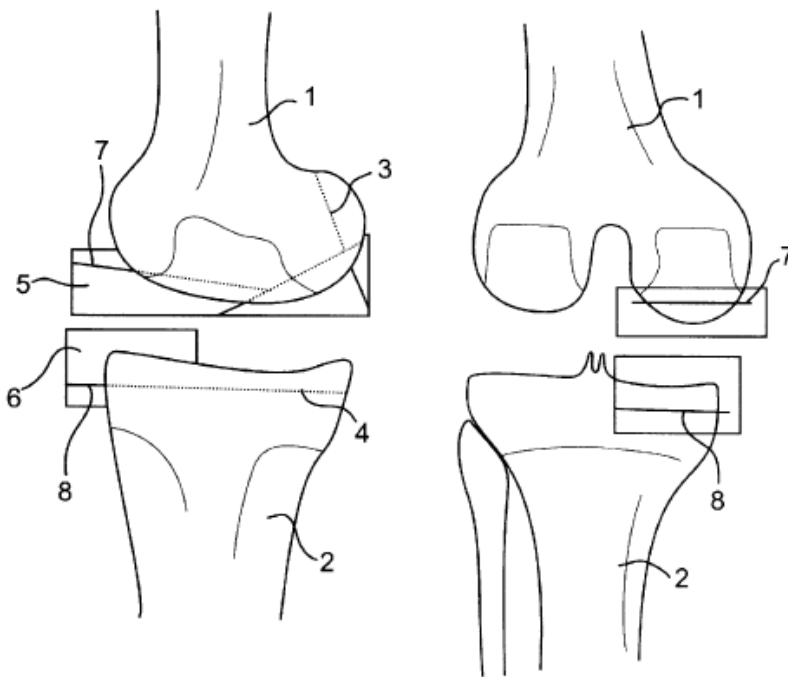
Claims of US 9,295,482	Invalidity Contentions
	<p>tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.</p> <ul style="list-style-type: none"> • Column 4, Lines 32-41 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative set. • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . <p style="margin-left: 40px;">virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones; . . .</p> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the</p>

Claims of US 9,295,482	Invalidity Contentions
	<p>state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>
[1.B.v] wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 2, Lines 39-53 <ul style="list-style-type: none"> ○ An object of the present invention is therefore to provide a method of producing an endoprosthesis as a joint substitute for knee joints which minimises the error rate in connection with a surgical intervention on a damaged knee joint and which further

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	<p>optimizes the surgical intervention in respect of the possibility to allow a very close adaption at least of the femoral and tibial components of an endoprosthesis to the contours of the bone joints as specifically prepared on respective surfaces during a surgical intervention for snugly fitting thereto the components of the endoprosthesis.</p> <p>A further object of the present invention relates to the provision of an operative set for carrying out operations on damaged knee joints which will allow a practically readymade surgical intervention on a damaged knee joint as accompanied with less pain for the patient.</p> <ul style="list-style-type: none"> • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63 <ul style="list-style-type: none"> ○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoin and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 1 <ul style="list-style-type: none"> ○  • Column 5, Lines 20-23 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 40 – Column 4, Line 5

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones. ● Column 4, Line 64 – Column 5, Line 2 ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing

Claims of US 9,295,482	Invalidity Contentions
	<p>areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint.</p> <ul style="list-style-type: none">• Figure 2<ul style="list-style-type: none">○• Column 5, Line 20-27

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtually transferred during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid. • Column 4, Lines 32-41 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative set. • Claim 1 <ul style="list-style-type: none"> ○ A method of producing an endoprosthesis as a joint substitute for knee joints comprising . . . virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones; . . .

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Claim 4 <ul style="list-style-type: none"> ○ The method of claim 1, wherein the tomographic images are prepared by a nuclear spin resonance tomography. • Column 4, Lines 20-24 <ul style="list-style-type: none"> ○ The same "Rapid Prototyping" may also be used for the preparation of corresponding STL patterns made, e.g., of epoxy resin and provided with those guiding slots at the marked severing areas which have been virtually transferred during the preceding step. <p><u>U.S. 4,759,350 to Dunn (incorporated by reference in Schuster I)</u></p> <ul style="list-style-type: none"> • Column 6, Line 45 to Column 7, Line 68 <ul style="list-style-type: none"> ○ The present invention is in a system of instruments for use by a surgeon to provide for a restoration of normal lower extremity alignment of knee prosthesis components that are aligned relative to the patient's mechanical axis. The patient's mechanical axis is established by drawing a line on an appropriate x-ray from the patient's hip to ankle when the patient is in a stable, erect attitude. In practice, this mechanical axis is generally a line or axis drawn through the longitudinal center of the patient's tibia that intersects the center of the femur head. This axis must be measured for each particular patient, and, for the purposes of this invention, is generally then referenced from the patient's anatomic axis, which is the axis through an intramedullary channel in the femur bone. This angular difference from the vertical of the mechanical to anatomic axis has been found in practice to be usually five degrees (5) and, in a few women it has been found to be six degrees (6'). Occasionally, in patients who have had total hip arthroplasty with a femoral component that has more valgus in the shaft angle than usual, or in the patient with coxa valga, this angular difference will be four degrees (4) or even three degrees (3). In a very

Claims of US 9,295,482	Invalidity Contentions
	<p>rare patient who has significant coxa valga or a broad pelvis with a long femoral neck the angular difference may be seven degrees (7) or eight degrees (8). Accordingly, the present invention provides for sitting a range of angles of a cutting guide relative to the anatomic axis, as will be discussed later herein, between zero degrees (0) and eight degrees (8). . . .</p> <p>On the developed radiograph, as illustrated in FIG. 1, a line is drawn from the center of the femoral head to the center of the distal femur at the knee with a second line drawn down the middle of the distal femoral shaft in the area where an intramedullary alignment rod is fitted to reproduce the anatomic axis of the femur. The angle between these two lines is the angle that is reproduced during surgery using the instruments of the present invention.</p> <p>The above sets out a preferred practice for determining the patient's mechanical axis in relation to their anatomic axis. Once the anatomic axis is established, the amount of distal femur removal can be calculated, providing for cutting that bone end to form a plane surface that is perpendicular to the mechanical axis using the system of the present invention as set hereinbelow. In the vein of locating the patient's mechanical axis and therefrom making perpendicular cuts across the distal femur and proximal tibia, for a preferred Miller/-Galante tibial component the proximal tibia is to be cut at an angle often degrees (10) to a plane perpendicular to that mechanical axis. To prepare the proximal tibia, the present invention utilizes a guide that is used independently from the distal femur preparation instrument and is fitted and secured between the center of the upper tibia and the ankle. This guide, once installed, provides a cutting guide platform for cutting across the proximal tibia at the desired angle often degrees (10) below a plane that is perpendicular to the patient's mechanical axis.</p> <p>FIG. 1, as set out above, illustrates the relationship between a patient's femur and tibia bones as would be shown in an A/P radiograph, therein the tibia is shown at 30 and the femur is shown at 31. FIG. 1 identifies the patient's mechanical and anatomic axis and</p>

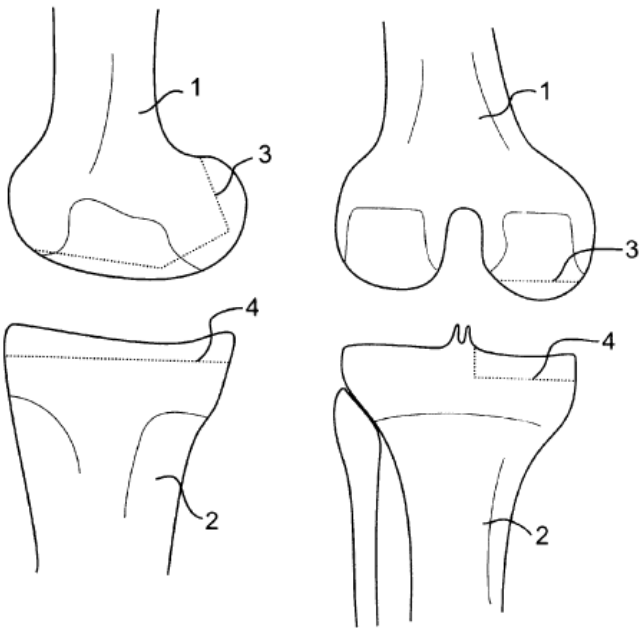
Claims of US 9,295,482	Invalidity Contentions
	<p>a transverse axis that is perpendicular to the mechanical axis of the respective opposing faces identified at 33 and 32 of the distal femur and proximal tibia. The mechanical axis is shown as a line drawn from approximately the center of the distal femur end to the femur head 34. In FIG. 1 therefore the angle between the mechanical axis and the anatomic is established by measuring the angle difference of the two axis as shown in the x-ray, which angle, as set out above, is usually five degrees (5') or six degrees (6').</p> <ul style="list-style-type: none">• Figures 1

Claims of US 9,295,482	Invalidity Contentions
	<div data-bbox="636 332 959 1190" data-label="Image"> <p>FIG. 1</p> </div> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants'</p>

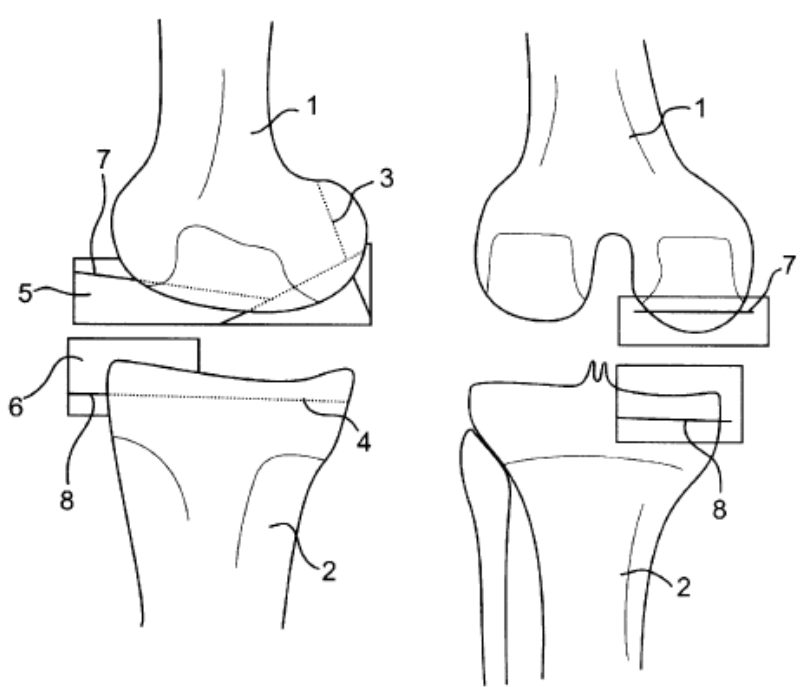
Claims of US 9,295,482	Invalidity Contentions
	<p>Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>
<p>[17-pre] A joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient, comprising:</p>	<p>To the extent the preamble is limiting, Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint. <i>See</i> analysis and material cited for claim 1-pre, above.</p> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

Claims of US 9,295,482	Invalidity Contentions
	<p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 1-pre, above.</p>
[17.A] an implant; and	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious an implant, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint. <i>See</i> analysis and material cited for claim 1.A, above.</p> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 1.A, above.</p>
[17.B] a block having a patient-specific surface and a guide:	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a block having a patient-specific surface and a guide, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>See analysis and material cited for Claim 1, above. As further examples, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 2, Lines 39-53 <ul style="list-style-type: none"> ○ An object of the present invention is therefore to provide a method of producing an endoprosthesis as a joint substitute for knee joints which minimises the error rate in

Claims of US 9,295,482	Invalidity Contentions
	<p>connection with a surgical intervention on a damaged knee joint and which further optimizes the surgical intervention in respect of the possibility to allow a very close adaption at least of the femoral and tibial components of an endoprosthesis to the contours of the bone joints as specifically prepared on respective surfaces during a surgical intervention for snugly fitting thereto the components of the endoprosthesis.</p> <p>A further object of the present invention relates to the provision of an operative set for carrying out operations on damaged knee joints which will allow a practically readymade surgical intervention on a damaged knee joint as accompanied with less pain for the patient.</p> <ul style="list-style-type: none"> • Column 2, Lines 59-64 <ul style="list-style-type: none"> ○ In accordance with a preferred embodiment of the present invention a method of producing an endoprosthesis as a joint substitute for knee joints is started by preparing a preoperative tomographic image of the damaged knee joint. The tomographic image could be prepared either by a computed tomography or by a nuclear spin resonance tomography which allows to define very sharp contours of the damaged knee joint as a correspondingly optimal precondition for all of the subsequent steps of this method. • Column 2, Line 65-Column 3, Line 1 <ul style="list-style-type: none"> ○ The tomographic image of the damaged knee joint is then virtually altered for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to the contours of a healthy knee joint. • Column 4, Lines 60-63

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none">○ FIG. 1 illustrates schematically the step of preparing a preoperative tomographic image of a damaged kneejoint and the preparation of virtual severing areas for the damaged femoral and tibial components of the joint.• Figure 1<ul style="list-style-type: none">○• Column 5, Lines 20-23

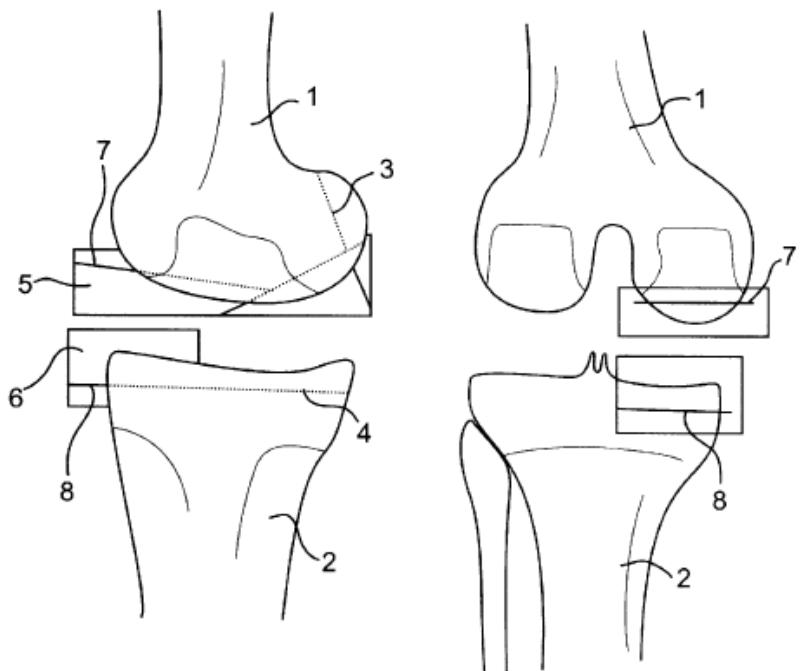
Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint • Column 3, Lines 40 – Column 4, Line 5 ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 4, Line 64 – Column 5, Line 2 <ul style="list-style-type: none"> ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint. • Figure 2 <ul style="list-style-type: none"> ○ 

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtually transferred during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid. • Column 4, Lines 32-41 <ul style="list-style-type: none"> ○ The operation of the patient will be carried out by first opening the knee joint and by subsequently severing the damaged components first at the tibia and then on the femoral bone. This particular severing will be carried out by using the implantation aid as a guide aid for guiding an oscillating sawing blade along the guiding slots of the implantation aid. The joint bones will thereby receive resection areas which exactly correspond with the severing areas as provided on the tibial and femoral components of the endoprosthesis of the particular operative set. <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p>

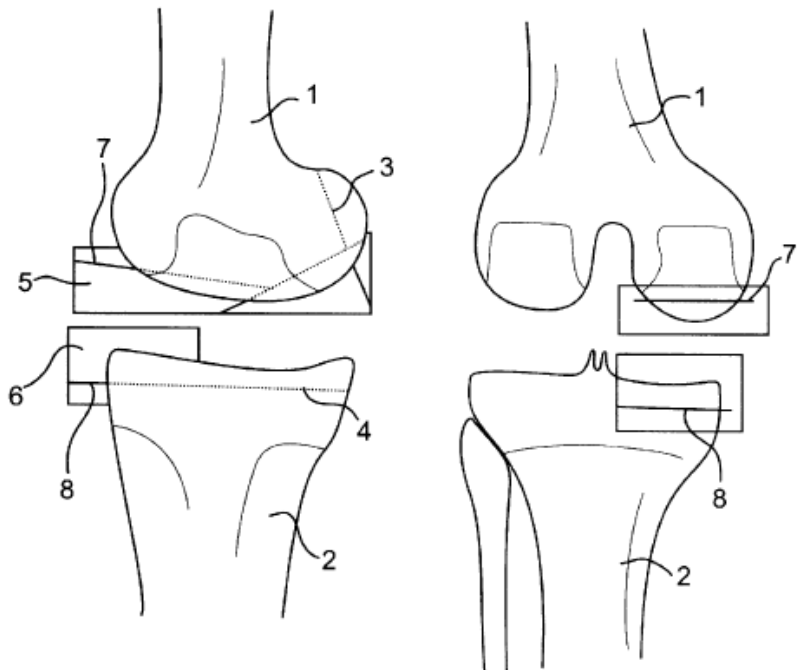
Claims of US 9,295,482	Invalidity Contentions
	<p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 (“The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues.”); Column 5, Lines 41-47 (“Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.”).</p>
<p>[17.B.i] the patient-specific surface having a first portion configured to have a shape that is substantially a negative of an articular surface of the diseased or damaged joint,</p>	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious the patient-specific surface having a first portion configured to have a shape that is substantially a negative of an articular surface of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff’s infringement contentions and complaint.</p> <p><i>See</i> analysis and material cited for claim 1.B.i, above. As further examples, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 3, Lines 40 – Column 4, Line 5 <ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation

Claims of US 9,295,482	Invalidity Contentions
	<p>aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones.</p> <ul style="list-style-type: none"> • Column 4, Line 64 – Column 5, Line 2 <ul style="list-style-type: none"> ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint. • Figure 2

Claims of US 9,295,482	Invalidity Contentions
	<p>○</p>  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are virtualty transferred during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.

Claims of US 9,295,482	Invalidity Contentions
	<p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damaged knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>
<p>[17.B.ii] a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,</p>	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint.</p> <p>For example, see the following illustrative citations to Schuster I:</p> <ul style="list-style-type: none"> • Column 3, Lines 40 – Column 4, Line 5

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> ○ This marking of severing areas is also used for virtually preparing tomographic images of femoral and tibial templates for the femoral and tibial components of the damaged knee joint as corresponding separate visual patterns of an implantation aid which by virtually transferring the marked severing areas for the preparation of such templates will therefore fit snugly to the damaged knee joint. As in case of the preparation of the femoral and tibial components of the endoprosthesis the virtually prepared tomographic image of such femoral and tibial templates may directly be used for the preparation of the associated implantation aid. The marked severing areas showing up on the templates are transferred to the corresponding components of the implantation aid and serve as corresponding guiding slots of a guide aid for guiding, e.g., an oscillating sawing blade during the factual operation of the damaged knee joint when the damaged knee joint components are then factually severed from the joint bones. When preparing the virtual image of the femoral and tibial templates it is therefore essential that the implantation aid and therefore in the first place the femoral and tibial templates receive a very exact positioning on the damaged knee joint so that with the oscillating sawing blade correspondingly exact resection surfaces will be obtained on the joint bones for fitting snugly to the associated surfaces of the femoral and tibial components of the endoprosthesis for which the marked severing areas have been virtually transferred for the preparation of such templates. It should therefore be preferred to design such templates and therefore also their corresponding implantation aids, e.g., in the form of caps for obtaining an enveloping of the severing areas which therefore identify negative images of the resection areas as provided by the sawing blade on the associated joint bones. ● Column 4, Line 64 – Column 5, Line 2 ○ FIG. 2 illustrates schematically the virtual preparation tomographic images of femoral and tibial templates as visual patterns of an implantation aid whereby the severing areas are virtually transferred as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint.

Claims of US 9,295,482	Invalidity Contentions
	<ul style="list-style-type: none"> • Figure 2 <ul style="list-style-type: none"> ○  <ul style="list-style-type: none"> • Column 5, Line 20-27 <ul style="list-style-type: none"> ○ In the drawings, numerals 1 and 2 refer to the femoral bone and the tibia of a knee joint. Numerals 3 and 4 refer to the virtual severing areas as prepared on the preoperative tomographic image of a damaged knee joint which severing areas are

Claims of US 9,295,482	Invalidity Contentions
	<p>virtualty transfered during a virtual preparation of tomographic images of femoral and tibia templates 5 and 6 for which the severing areas are exemplified as virtual guiding slots 7 and 8 of a guide aid.</p> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See, e.g.</i>, Column 4, Line 50-56 ("The preparation of the endoprosthesis could also include the preparation of a component which will be used for the patella of the damage knee joint. The method could further be also applied to surgical interventions of other joints such as for example of the ankle joint or of finger and toe joints and it could also be used for the reconstruction of bone and cartilage tissues as well as soft tissues."); Column 5, Lines 41-47 ("Although several embodiments of the present invention and its advantages have been described in detail, it should be understood that mutations, changes, substitution, transformations, modifications, variations and alterations can be made without departing from the teachings of the present invention, the spirit and scope of the invention being set forth by the appended claims.").</p>
[17.B.iii] wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint; and	Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint. <i>See</i> analysis and material cited for claim 1.B.iii, above.

Claims of US 9,295,482	Invalidity Contentions
	<p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 1.B.iii, above.</p>
[17.B.iv] the guide being sized and shaped to accommodate a surgical tool and	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders obvious the guide being sized and shaped to accommodate a surgical tool, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint. <i>See</i> analysis and material cited for claim 1.B.iv, above.</p> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 1.B.iv, above.</p>

Claims of US 9,295,482	Invalidity Contentions
<p>[17.B.v] have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.</p>	<p>Schuster I discloses (explicitly, implicitly, and inherently) and also renders the guide having a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint, at least under the claim constructions implicit in Plaintiff's infringement contentions and complaint. <i>See</i> analysis and material cited for claim 1.B.v, above.</p> <p>Further, to the extent that ConforMIS contends Schuster I does not anticipate the claim, including this limitation, it would have been obvious to one of ordinary skill in the art in light of the disclosures in this reference, a POSITA's knowledge, ordinary creativity of one of ordinary skill in the art, and the state of the art, including the prior art described in Exhibit A. Additionally, the claim would have been obvious in light of Schuster I and one or more of the prior art references identified in Defendants' Invalidity Contentions, including but not limited to the particular exemplary references discussed with respect to this element in Exhibit A, for the reasons described in Exhibit A, this chart, and Defendants' Invalidity Contentions.</p> <p>For example, Schuster I teaches that modifications and variations to its methods and apparatuses would be apparent to and within the skill set of a person of ordinary skill in the art. <i>See</i> analysis and material cited for claim 1.B.v, above.</p>

Exhibit 4

Exhibit A – Obviousness Under 35 U.S.C. § 103

As described in Defendants' Invalidity Contentions, every Asserted Claim of the Asserted Patents, in addition to being anticipated, also was obvious to those of ordinary skill in the art at the time of the alleged invention. This is illustrated, for example, by the claim charts attached to Defendants' Invalidity Contentions ("Charted References"), which are incorporated herein by reference. It would have been obvious to combine any of the references identified in Defendants' Invalidity Contentions, including the particular references identified in the Charted References, which are analogous art, at least because such combinations: combine prior art elements according to known methods to yield predictable results; are a simple substitution of one known element for another to obtain predictable results; use known techniques to improve similar devices, methods, or products in the same way; apply a known technique to a known device, method, or product ready for improvement to yield predictable results; are obvious to try, including because they choose from a finite number of identified, predictable solutions with a reasonable expectation of success; use a known work in one field of endeavor to prompt variations of it for use in either the same field or a different one based on design incentives or other market forces since the variations are predictable to one of ordinary skill in the art; and contain some teaching, suggestion, or motivation that would have led one of ordinary skill in the art to modify or combine the references to arrive at the Asserted Claims. It would also have been obvious to combine these disclosures with general knowledge of a person of ordinary skill in the art at the time of the alleged invention to arrive at the Asserted Claims.

This Exhibit also includes specific non-limiting examples of additional references, other than the Charted References, which would be obvious to combine for the same reasons, and which further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions.

- Junichi Arima et al., *Femoral Rotational Alignment, Based on the Anteroposterior Axis in Total Knee Arthroplasty in a Valgus Knee*, 77 J. BONE & JOINT SURGERY 1331 (1995) ("Arima")
- RONALD J. ALLEN ET AL., ARTHRITIS OF THE HIP & KNEE: THE ACTIVE PERSON'S GUIDE TO TAKING CHARGE (1998) ("ARTHRITIS OF THE HIP & KNEE")
- THE COLUMBIA PRESBYTERIAN OSTEOARTHRITIS HANDBOOK (Ronald P. Grelsamer & Suzanne Loebl eds., 1996) ("OSTEOARTHRITIS HANDBOOK")
- D. G. Eckhoff et al., *Malrotation Association with Implant Alignment Technique in Total Knee Arthroplasty*, 321 CLINICAL ORTHOPAEDICS & RELATED RSCH. 28 (1995) ("Eckhoff et al.")
- DePuy, P.F.C. Sigma Knee System
- EP 0 908 836 A2 to John Christian Vomlehn ("Vomlehn")
- Laith M. Jazrawi et al., *The Accuracy of Computed Tomography for Determining Femoral and Tibial Total Knee Arthroplasty Component Rotation*, 15 J. ARTHROPLASTY 761 (2000) ("Jazrawi et al.")

- KENNETH A. KRACKOW, THE TECHNIQUE OF TOTAL KNEE ARTHROPLASTY (1990) (“Krackow”)
- Klaus Radermacher et al., *Computer Assisted Orthopaedic Surgery with Image Based Individual Templates*, 354 CLINICAL ORTHOPAEDICS & RELATED RSCH. 28 (1998) (“Radermacher CAOS”)
- Klaus Radermacher, *Computer-Assisted Surgery Planning and Execution Using Customized Processing Templates in Orthopedics* (1999) (“Radermacher Thesis”)
- SURGERY OF THE KNEE (John N. Insall & W. Norman Scott eds., 3d ed. 2001) (“Insall”)
- SURGICAL TECHNIQUES IN TOTAL KNEE ARTHROPLASTY (Giles R. Scuderi & Alfred J. Tria, Jr. eds., 2002) (“Scuderi & Tria”)
- U.S. Patent No. 4,841,975 to Steven T. Woolson (“Woolson”)
- U.S. Patent No. 6,106,529 to Richard C. Techiera (“Techiera”)
- WO 2000/034346 to Eugene J. Alexander et al. (“Alexander”)
- WO 2004/112610 to Curt A. Stone et al. (“Stone”)

Additionally, Conformis’s disclosures regarding the priority dates of its own patents and patent applications is unclear and deficient. Conformis recently disclosed, in response to the Court’s order compelling supplemental discovery, that the priority dates set forth in its initial responses for the ’304, ’161, ’129, and ’482 patents were inaccurate, the dates appear to still be inaccurate, and Conformis to date has refused to further supplement, to provide correct dates for the ’745, ’780, and ’026 patents, or to provide accurate conception/reduction to practice dates. Defendants reserve the right to use any of the asserted patents and the applications cited therein as prior art to other asserted patents. Furthermore, Defendants reserve the right to rely on other references, including the following, as evidence of the state of the art and as 35 U.S.C. § 102 and 35 U.S.C. § 103 references depending on the ultimate positions taken by Conformis regarding the priority dates of its patents:

- EP 1 074 229 A2 to Luis Schuster
- U.S. Patent No. 8,672,945 to Stéphane Lavallee et al.
- U.S. Publication No. 2007/0226986 to Park et al.
- U.S. Publication No. 2007/0233141 to Park et al.
- N. Schiffers et al., *Planning and Execution of Orthopedic Surgery Using Individualized Templates*, 29 DER ORTHOPÄDE 636 (2000)

Conformis appears to be pursuing overly broad constructions of various limitations of the asserted claims in an effort to piece together an infringement claim where none exists and to accuse methods that do not practice the claims. This exhibit takes into account Conformis’s overly broad construction of the claim limitations, including the constructions implicit in its infringement contentions. Any assertion that a particular limitation is disclosed by a prior art reference or references may be based in whole or in part on Conformis’s apparent

constructions and is not intended to be, and is not, an admission that such constructions are supportable or proper. Rather, any construction broad enough to allegedly read on any accused method would necessarily read on the prior art, further confirming that the claims are invalid.

Herein, specific examples and motivations to combine are provided for each element. However, there are overlapping aspects to many of the elements. Accordingly, it should be recognized that disclosure relating to an aspect of a limitation (e.g., a particular material, type of tool or aperture, or applicability to a particular part of a surgery) is generally applicable to other limitations in which it may also appear.

A. “Surface” Limitations

Surfaces and patient-specific surfaces, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff’s infringement contentions:

Patent	Claim	Claim Language
026	15	at least one surface for engaging a first articular surface of a joint,
026	15	the at least one surface being substantially a negative of portions or all of the first articular surface
026	52	at least one surface for engaging a first cartilage surface of a joint,
026	52	the at least one surface being substantially a negative of portions of the first cartilage surface;
129	1	a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged knee joint of the patient,
161	1	a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and
161	19	a mold having an internal surface that substantially conforms to the shape of the joint of the patient and includes joint information derived from image data of the joint of the patient; and
304	1	a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and

Patent	Claim	Claim Language
304	4	The surgical instrument of claim 1, wherein the internal surface substantially conforms to the shape of a surface of the joint of the patient, wherein the surface of the joint includes a cartilage surface of the joint and a subchondral bone surface of the joint.
129	1	the patient-specific surface including cartilage information derived from image data of the diseased or damaged knee joint of the patient; and
161	1	a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and
161	19	a mold having an internal surface that substantially conforms to the shape of the joint of the patient and includes joint information derived from image data of the joint of the patient; and
304	1	a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and
304	31	a mold having an internal surface that substantially conforms to the shape of a cartilage surface of the joint of the patient and includes joint information derived from image data of the joint of the patient; and
482	1	a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint,
482	1	the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint,
482	17	a block having a patient-specific surface and a guide:
482	17	the patient-specific surface having a first portion configured to have a shape that is substantially a negative of an articular surface of the diseased or damaged joint,
482	17	a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,
745	1	a cutting block having a patient-specific surface and
745	1	at least a portion of the patient-specific surface having a shape that is substantially a negative of a corresponding cartilage surface of the diseased or damaged joint; and
780	1	a contact surface for engaging a first articular surface of the joint of the patient,

Patent	Claim	Claim Language
780	1	the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface;
780	3	engaging the contact surface of the first template with the first articular surface of the joint, and

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Asserted Patents

- '745 Patent, 4:66-5:4; '482 Patent, 30:34-52; '161 Patent, 30:34-52; '129 Patent, 12:17-35; '304 Patent, 12:17-35; '026 Patent, 22:57-23:7; '780 Patent, 23:1-19
 - As will be appreciated by those of skill in the art, the practice of the present invention employs, unless otherwise indicated, conventional methods of x-ray imaging and processing, x-ray tomosynthesis, ultrasound including A-scan, B-scan and C-scan, computed tomography (CT scan), magnetic resonance imaging (MRI), optical coherence tomography, single photon emission tomography (SPECT) and positron emission tomography (PET) within the skill of the art. Such techniques are explained fully in the literature and need not be described herein. See, e.g., X-Ray Structure Determination: A Practical Guide, 2nd Edition, editors Stout and Jensen, 1989, John Wiley & Sons, publisher; Body Conn.: A Practical Approach, editor Slone, 1999, McGraw-Hill publisher; X-ray Diagnosis: A Physician's Approach, editor Lam, 1998 Springer-Verlag, publisher; and Dental Radiology: Understanding the X-Ray Image, editor Laetitia Brocklebank 1997, Oxford University Press publisher. See also, The Essential Physics of Medical Imaging (2nd Ed.), Jerrold T. Bushberg, et al.
- '745 Patent, 31:57-32:3; '482 Patent, 32:3-15; '161 Patent, 32:3-16; '129 Patent, 13:51-64; '304 Patent, 13:54-67; '026 Patent, 24:24-37; '780 Patent, 24:37-50
 - As will be appreciated by those of skill in the art, imaging techniques suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss include the use of x-rays, magnetic resonance imaging (MRI), computed tomography scanning (CT, also known as computerized axial tomography or CAT), optical coherence tomography, ultrasound imaging techniques, and optical imaging techniques. (See, also, International

Patent Publication WO 02/22014 to Alexander, et al., published Mar. 21, 2002; U.S. Pat. No. 6,373,250 to Tsoref et al., issued Apr. 16, 2002; and Vandeberg et al. (2002) Radiology 222:430-436). Contrast or other enhancing agents can be employed using any route of administration, e.g. intravenous, intra-articular, etc.

- '745 Patent, 32:31-48; '482 Patent, 32:42-59; '161 Patent, 32:44-61; '129 Patent, 14:6-23; '304 Patent, 14:9-26; '026 Patent, 24:65-25:15; '780 Patent, 25:11-28
 - For discussions of the basic NMR principles and techniques, see MRI Basic Principles and Applications, Second Edition, Mark A. Brown and Richard C. Semelka, Wiley-Liss, Inc. (1999). For a discussion of MRI including conventional T1 and T2-weighted spin-echo imaging, gradient recalled echo (GRE) imaging, magnetization transfer contrast (MTC) imaging, fast spin-echo (FSE) imaging, contrast enhanced imaging, rapid acquisition relaxation enhancement (RARE) imaging, gradient echo acquisition in the steady state (GRASS), and driven equilibrium Fourier transform (DEFT) imaging, to obtain information on cartilage, see Alexander, et al., WO 02/22014. Other techniques include steady state free precision, flexible equilibrium MRI and DESS. Thus, in preferred embodiments, the measurements produced are based on three-dimensional images of the joint obtained as described in Alexander, et al., WO 02/22014 or sets of two-dimensional images ultimately yielding 3D information.
- '745 Patent, 43:4-15; '482 Patent, 43:14-24; '161 Patent, 43:14-25; '129 Patent, 17:59-18:3; '304 Patent, 17:65-18:6; '026 Patent, 35:37-47; '780 Patent, 35:50-61
 - Devices suitable for obtaining intraoperative measurements of cartilage or bone or other articular structures, and to generate a topographical map of the surface include but are not limited to, Placido disks, optical measurements tools and device, optical imaging tools and devices, and laser interferometers, and/or deformable materials or devices. (See, for example, U.S. Pat. No. 6,382,028 to Wooh et al., issued May 7, 2002; U.S. Pat. No. 6,057,927 to Levesque et al., issued May 2, 2000; U.S. Pat. No. 5,523,843 to Yamane et al. issued Jun. 4, 1996; U.S. Pat. No. 5,847,804 to Sarver et al. issued Dec. 8, 1998; and U.S. Pat. No. 5,684,562 to Fujieda, issued Nov. 4, 1997).
- ii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor
- Paragraph 60
 - *Berez* describes patient-specific cutting guides for use in joint arthroplasty procedures. Ex.B at Title, Abstract; *see also id.* ¶¶ [0265]-[0331]. The cutting guides have a surface that will match a portion of an articular or a bone surface. *Id.* ¶ [0266].

The guides also have apertures, slots, and/or holes to accommodate surgical tools such as saws and drills. *Id. Berez* explains that "[t]ypically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general [cutting guide] orientation for subsequent placement of an articular repair system [(implant)] or for facilitating placement of the articular repair system [(implant)]." *Id.* ¶ [0267].

- Paragraph 65
 - In particular, *Radermacher* proposes a cutting guide "by which parts of the surface of an arbitrary osseous [(bone)] structure which is to be treated and is intraoperatively accessible to the surgeon, are copied [into the inner surface of the cutting guide] as a negative image without undercut and in a mechanically rigid manner." *Id.* at 10. "[C]utting, boring, milling and other treatment steps" can be included in the cutting guide such that the preoperative planning" is realized by simply setting the [cutting guide] onto the exposed surface of the bone." *Id.* at 11.
- Paragraph 68
 - *Radermacher* describes reconstructing tomographic images into a three-dimensional image of the osseous structure. *Id.* at 12. And with a computer system, a "three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure" is generated. *Id.* *Radermacher* explains that this negative mold of the bone surface can be used to construct the contact surface of the cutting guide. *Id.*
- Paragraph 69
 - In addition, cutting paths may be included "in/on the basic body" of the cutting guide. *Id.* at 13. The cutting paths are oriented or constructed "relative to the [three-dimensional] reconstruction of the osseous structure" to "effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by [preoperative] planning." *Id.* That is, the treatment steps defined in preoperative planning "can be exactly transferred since, relative to the osseous structure, the [cutting paths] can be brought exactly into the positions defined during [preoperative] planning." *Id.* at 14-15. "To this purpose, the [cutting guide] with the faces of the negative mold is set under mating engagement onto the then exposed bone surface . . . without any further intraoperative devices . . . and without intraoperative measuring and positioning work." *Id.* at 15. *Radermacher* notes that "nails, screws and the like" may be used to fix the cutting guide to the bone. *Id.* at 25.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught patient-specific surfaces, including patient-specific surfaces derived from image data, for engaging a surface of a patient's joint. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that the use of patient-specific surfaces can increase the accuracy of tool guide alignment and the resulting work done to the bone. Furthermore, the Charted References taught that the use of patient-specific surfaces can increase the efficiency of an operation. Additionally, many of the Charted References taught the use of patient-specific surfaces in tools for the same joint procedures, including total knee arthroplasty. Thus, a person of ordinary skill in the art would have been motivated by Charted References to include a patient-specific surface on a tool for knee or other joint arthroplasty.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Vomlehn

• Abstract

- A system for constructing a reference structure intended to fit flush against an anchor site of a subject is used to anchor and guide medical equipment, or used for accurate placement of fasteners into the anchor site. The present invention employs a medical imaging device (11) which acquires data of internal structures of the subject. This data is segmented (19) into discrete solid structures. These solid structures are displayed on a user interface (23) as a 3D computer model. The user then selects a structure and an anchor site on the structure which a fastener is to be positioned. The user may also interactively indicate, through the user interface, a location and orientation in which the fastener is to be inserted. A design device (25) creates a surgical guide having a mating face which fits flush against the anchor site. The guide may have pre-drilled guide holes for receiving a surgical instrument, such as a drill for drilling into the anchor site. It may have an attachment structure for attaching medical equipment. Several probe holes may also be made which receive a probe and intersect with the anchor site. Markings on the probe indicate if the mating face is flush against the anchor site.

- [0015]
 - A medical imaging means acquires medical imaging data of the subject 1 in a region including the anchor site. The user may operate a user interface to steer the medical imaging means to the proper region.
- [0016]
 - A segmentation device identifies a segmented structure being contiguous locations in the imaging data having the data values within a defined range.
- [0018]
 - A design device, which may be a conventional computer aided design (CAD) device, creates a computer model of a reference structure having a mating surface designed to fit flush with said subject's anchor site.
- [0028]
 - A subject 1 on which the procedure is to be performed, is imaged with a medical imaging device 11. Medical imaging device 11 may be a computed tomography (CT), magnetic resonance (MR), ultrasound, or positron emission tomography (PET) imaging device. Other types of medical imaging device may also be used which provide an image of internal organs of subject 1 and can provide an image of tracked targets 28.
- [0030]
 - A segmentation device 19 interacts with the volumetric data stored in data storage device 13 and determines data values within a range which may interactively be defined by user 3 via interface 17. These values are used to define a tissue type. Contiguous locations having the same tissue type are then determined. The set of all contiguous locations of the same tissue type are treated as a solid object or structure. This information may be stored in segmentation device 19 or data storage device 13.

- [0034]
 - User 3 also identifies an anchor site through user interface 17 interacting with graphics engine 21, which is a solid structure, typically bone, onto which reference structure 30 is attached.

- Figure 2

-

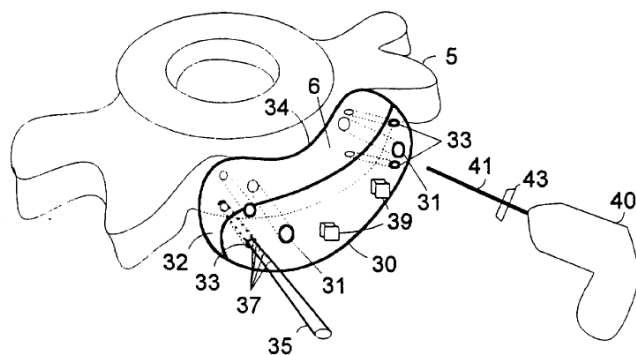


Fig. 2

A person of ordinary skill in the art would have been motivated to combine the teachings of Vomlehn with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the teachings in Vomlehn could be applied to a wide variety of orthopedic procedures, including total knee arthroplasty. *See, e.g.*, [0001] ("The present invention relates to computer-aided construction of a reference structure to be attached to a subject and act as a guide in medical procedures."); [0002] ("In various medical procedures, it is necessary to attach a piece of medical equipment into a solid structure of the subject."). Furthermore, Vomlehn teaches that its approach can increase the accuracy of medical procedures and eliminate estimation by surgeons or the use of intraoperative imaging. *See, e.g.*, [0006] ("Typically, these pins or screws have been inserted by a surgeon who visually, or by 'feel', finds the approximate location where the screw or pin should be entered, and drills a hole at that location. The screw or pin is inserted into the hole."); [0007] ("Sometimes, during surgery, two dimensional (2D) snapshots such as x-rays or magnetic resonance (MR) images may be obtained"); [0013]-[0014] ("Currently there is a need for a device which may be attached to a subject and act as a reference structure to guide instruments during medical procedures. The

present invention constructs a reference structure intended to be attached to a solid anchor site of a subject.”). Thus, to the extent not disclosed, a POSITA would be motivated to include a patient-specific surface.

ii. Radermacher CAOS

- Page 28

- An alternative technique for computerized tomographic image based preoperative three-dimensional planning and precise surgery on bone structures using individual templates has been developed. For the preoperative customization of these mechanical tool guides, a desktop computer controlled milling device is used as a three-dimensional printer to mold the shape of small reference areas of the bone surface automatically into the body of the template. Thus, the planned position and orientation of the tool guide in spatial relation to bone is stored in a structural way and can be reproduced intraoperatively by adjusting the position of the customized contact faces of the template until the location of exact fit to the bone is found. No additional computerized equipment or time is needed during surgery. The feasibility of this approach has been shown in spine, hip, and knee surgery, and it has been applied clinically for pelvic repositioning osteotomies in acetabular dysplasia therapy.

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- In total knee arthroplasty accurate placement of implant components with respect to the individual mechanical axis of the leg is essential. Conventionally, modular mechanical devices corresponding to the intrinsic shape of the implant components are used to guide the osteotomies and bores for the preparation of the implant's seat. By mounting these conventional tool guide systems on an individual template as a basic customized reference, it is possible to reproduce the preoperatively planned position exactly even in the case of severely deformed bone.

- Figures 2A-B

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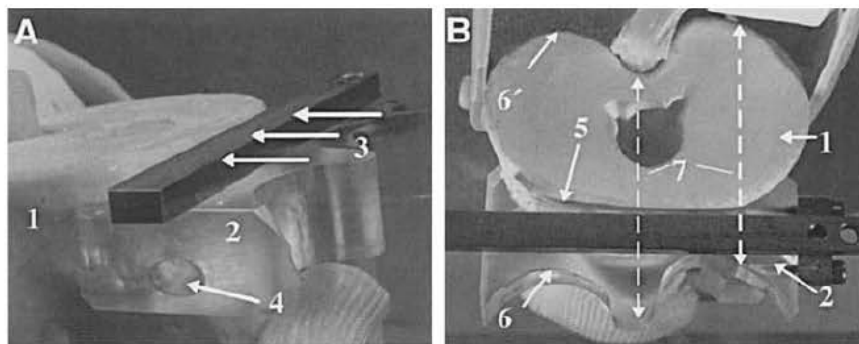


Fig 2A–B. Total knee arthroplasty: (A) laboratory investigation on a plastic bone model (1): individual template guiding the reference osteotomy (3) in tibial bone, optional fixation with a bone pin (4); (B) customized reference contact face (5) and copying profile (6) limiting cutting depth (7) to the dorsal contour (6) of tibial bone.

- Pages 31-32

- Figure 2 shows a feasibility study with a CT image based individual template for the reference tibial cut for total knee replacement on a plastic bone model.¹⁵ The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). In addition, topograms could be used to identify the bone axis. A conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone. The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes.

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- One main drawback of the approach is that it depends on preoperative CT imaging. Moreover, no percutaneous applications are possible (except in dental or maxillofacial surgery). Lamellar contact faces (with ribs or arrays of pins) could be manufactured to compensate to a limited extent for remaining soft tissue.¹⁵ But as in most sensor based surface registration techniques, the accuracy and reliability of this technique depends on the accessibility and appropriate intraoperative identification of the rigid reference structures segmented and modeled in the preoperative image data.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher CAOS and many of the references identified in Defendant's Invalidity Contentions, including the Charted References, come from the same field of invention and disclose patient-specific guides for total knee arthroplasty. Furthermore, Radermacher CAOS teaches that it can produce accurate bone cuts/work done to the bone. *See, e.g.*, Radermacher CAOS at 31-32 ("The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes."). Thus, a POSITA would be motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References.

iii. Radermacher Thesis

- Page 159

- Furthermore, on this basis, contact surfaces could also consist of hybrid contact surfaces for certain applications, i.e., be composed of both individually adapted surface portions and point-shaped contact portions in the form of metal pins or prefabricated metal webs. These could also penetrate soft tissue layers bluntly or sharply (e.g., longitudinally to the muscle fiber course) in anatomically uncritical areas and support the stencil on the bone in areas that should not be exposed, but ensure higher accuracy or stability of the referencing, e.g., due to the wider base.

- Pages 55-56

- 4.1 The concept of customized templates

The aim of the development is, on the one hand, to support the planning of surgical corrective procedures on bone structures by computer-aided preprocessing and reconstruction of three-dimensional CT image data, by linking additional information specific to the procedure or implant, and by additional tools for analysis and simulation. On the other hand, the preoperative planning information is to be stored and processed, in such a way, that intraoperative processing of the real bone structure, with conventional processing tools, is possible with corresponding accuracy.

The basic idea of the developed solution approach is to supplement the information of the exact spatial position, relative to the bone, which is missing from the conventional standard templates, based on individual CT image-based bone geometry model data, as well as the individual spatial planning of the surgeon. This is intended to exploit the advantages of conventional processing devices, to increase their accuracy, but also to create implementation aids for orthopedic procedures for which no processing devices are currently available.

Individual templates will be constructed on a patient-specific basis, using 3D reconstructions of preoperative CT image information. In addition to the surgical processing geometries, attachment areas of the template on the natural surface of the bony structure, which are conventionally accessible to the surgeon, are also defined as reference structures.

These segments of the individual bone surface geometry, reconstructed from CT data, are then structurally incorporated preoperatively into a corresponding template element under computer control, in such a way, that a clearly defined positive fit of the template, on the corresponding natural surface of the bone, is ensured and a planned position can thus be retrieved intraoperatively.* In addition, tool guides are integrated or adapted into the template elements, in position and orientation according to the planned processing geometry. . . . The solution concept is thus based on the process concept shown schematically in Figure 4-2, which is to be included in the further development and evaluation of the solution approach.

- Figure 4-1

○

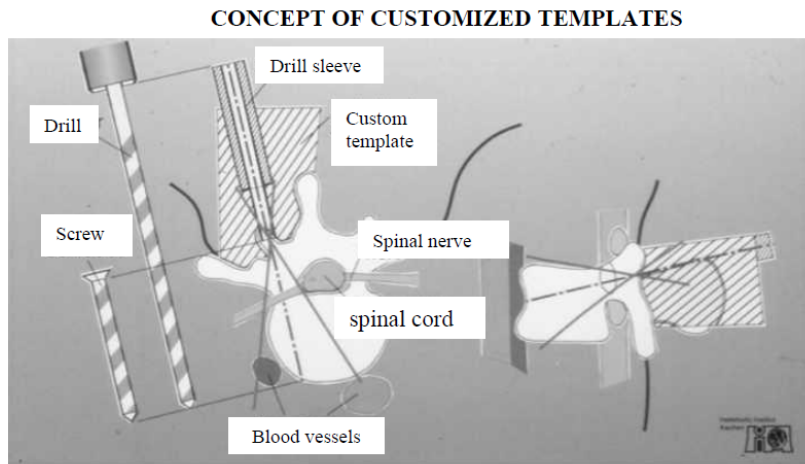


Figure 4-1: Schematic representation of the positioning of tool guides, by means of individually form-fitted reference surfaces or "contact surfaces", adapted to segments of the natural bone surface.

- Figure 4-37

○

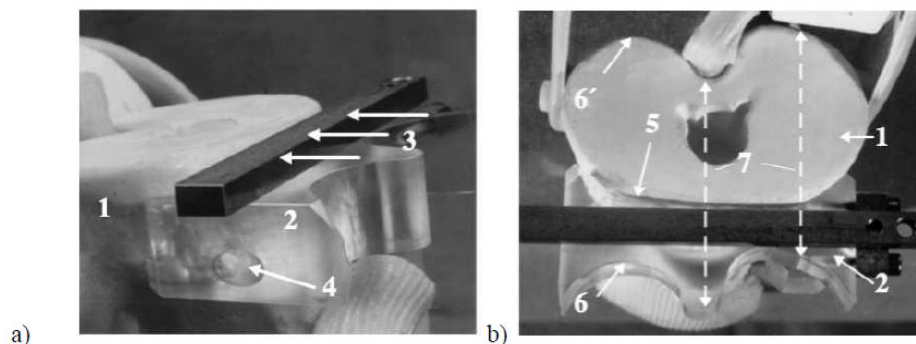


Figure 4-37: Individual template for guiding a tibial osteotomy for total knee arthroplasty – laboratory tests on a plastic model of a knee joint (1): a) The CT image-based customized template (2) precisely aligns the plane of the reference osteotomy (3). Optionally, the template can be fixed by bone pins (4). b) The CT image-based adapted contact surface (5) and contour to be copied (6) limit the depth of cut (7) to the dorsal surface contour (6') of the tibial bone.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach patient-specific templates for total knee arthroplasty. *See, e.g.,* Radermacher Thesis at 3 ("Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen."). Furthermore, Radermacher Thesis teaches that the disclosed individual templating technique can be applied to total knee arthroplasty. *See,*

e.g., Figure 4-37. Thus, a POSITA would be motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References.

iv. Alexander

- Page 2
 - Magnetic resonance imaging (MRI) is an accurate non-invasive imaging technique for visualization of articular cartilage in osteoarthritis, particularly in knees.
- Pages 11-12
 - In Figure 1, the first step 10 represents obtaining an image of the cartilage itself. This is typically achieved using MRI techniques to take an image of the entire knee and then, optionally, manipulating (e.g., "subtracting out" or "extracting") the noncartilage images as shown in step 12. Non-cartilage images typically come from bone and fluid. Preferably, the MRI is taken using external markers to provide reference points to the MRI image (step 11).
- Page 12
 - With a full 3D image captured, various "maps" or displays of the cartilage can be constructed to give a cartilage degeneration pattern. This is represented by step 16. One such display can, for example, be a color-coding of a displayed image to reflect the thickness for the cartilage. This will allow easy visual identification of actual or potential defects in the cartilage.
- Page 14
 - *Imaging Articular Cartilage*

In general, the joint of a patient is that place of union, more or less movable, between two or more bones. A joint comprises cartilage and other elements such as the accompanying bones on either side of the joint, fluid, and other anatomical elements. Joints are classified into three general morphological types: fibrous, cartilaginous, and synovial. This invention is particularly useful for assessing synovial joints, particularly the knee.

- Pages 14-15

- MRI, with its superior soft tissue contrast, is the best technique available for assessing tissue and its defects, for example articular cartilage and cartilage lesions, to obtain a cartilage degeneration can provide morphologic information about the area of damage. Specifically, changes such as fissuring, partial or full thickness cartilage loss, and signal changes within residual cartilage can be detected.

The reason MR imaging techniques are particularly suitable for cartilage is because they can provide accurate assessment of cartilage thickness, demonstrate internal cartilage signal changes, evaluate the subchondral bone for signal abnormalities, and demonstrate morphologic changes of the cartilage surface.

MRI provides several important advantages over other techniques in this invention. One advantage is good contrast between cartilage, bone, joint fluid, ligaments, and muscle in order to facilitate the delineation and segmentation of the data sets. Another is the coverage of the entire region of interest in a single scan within acceptable acquisition times.

- Page 40

- Since the algorithm for 3D surface registration of the femoral condyles also computes the surface normals for the medial and lateral femoral condyles on a pixel-by-pixel basis, it can form the basis for developing maps of cartilage thickness. Fig. 11 shows an example of a 2D map of cartilage thickness derived from the surface normals of the lateral femoral condyle. Figure 11A shows a proton density fast spin-echo MR image that demonstrates a focal cartilage defect in the posterior lateral femoral condyle (black arrows). White arrows indicate endpoints of thickness map. Figure 11 B is a 2D cartilage thickness map that demonstrates abrupt decrease in cartilage thickness in the area of the defect (arrows). The Δ thickness between neighboring pixels can be used to define the borders of the cartilage defect. Note diffuse cartilage thinning in area enclosed by the astericks (*).

- Figures 11A, 11B

○

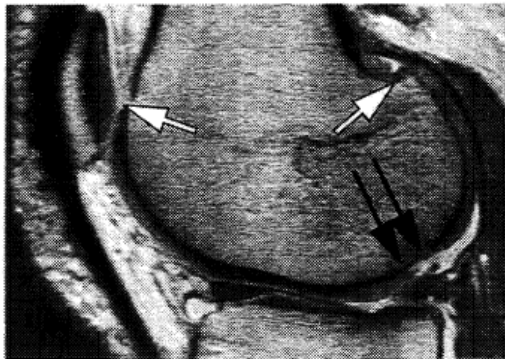


FIG. 11A

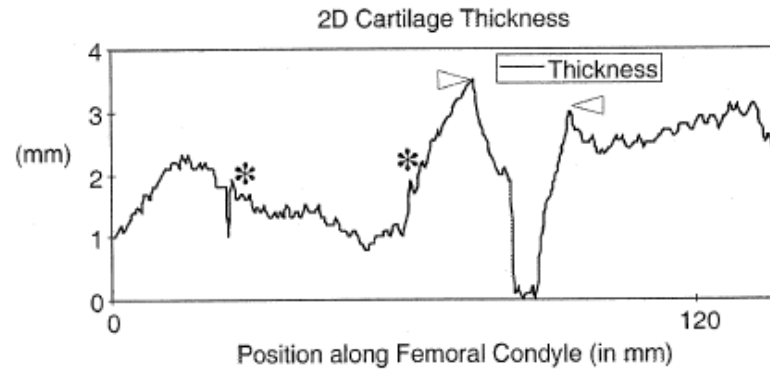


FIG. 11B

- Page 31

- Turning now to Figures 22A and 22B, one can see a 2D MRI (3D SPGR) and 3D cartilage thickness map. In A, the 2D MRI demonstrates a full thickness cartilage defect in the posterior lateral femoral condyle (arrows). Figure 22B shows a 3D cartilage thickness map generated using a 3D Euclidian distance transformation. The thickness of the articular cartilage is color encoded and displayed on a pixel-by-pixel basis along the 3D surface of the articular cartilage. The cartilage defect is black reflecting a thickness of zero (arrows) (M: medial, L: lateral, S: superior, I: inferior).

- Figures 22A, 22B

○

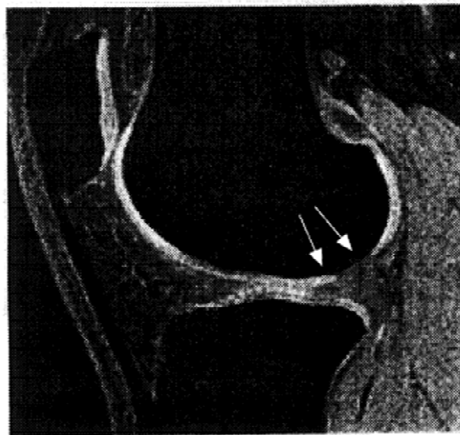


FIG. 22A

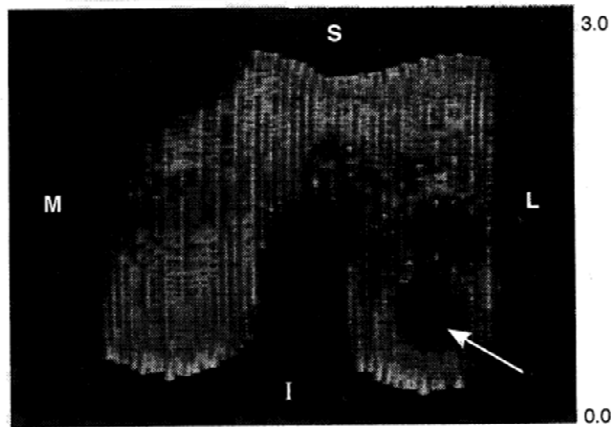


FIG. 22B

- Page 61

- An example of this type of visualization is given in Figure 18. The Figure shows what can be referred to as functional joint imaging. Figure 18A is a photograph demonstrating the position of the external markers positioned around the knee joint. The markers are filled with dilute Gd-solution. B is Sagittal 3D SPGR image through the medial femorotibial compartment. Two of the external markers are seen anteriorly as rounded structures with high signal intensity. C is 3D reconstruction of femoral and tibial bones (light grey), external 20 markers (dark grey), femoral cartilage (red), and tibial cartilage (blue) based on the original SPGR MR images.

- Figure 18C

○



A person of ordinary skill in the art would have been motivated to combine the teachings of Alexander with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Alexander teaches that "Magnetic resonance imaging (MRI) is an accurate non-invasive imaging technique for visualization of articular cartilage in osteoarthritis, particularly in knees" and that the imaging techniques taught in the Alexander are "particularly useful for assessing synovial joints, particularly the knee." Alexander at 2, 14. Many of the Defendants' identified references disclose tools for total knee arthroplasty, and specifically patient-specific tools for total knee arthroplasty with patient-specific surfaces constructed from image data that correspond to areas of the knee where cartilage can be present. Thus, it would be obvious to a POSITA to apply the imaging techniques taught in Alexander to construct a patient-specific surface using information from image data, including image data regarding cartilage and subchondral bone.

B. "Anatomical Relief" Limitations

Anatomic relief, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
026	15	at least a portion of the at least one surface further including an anatomical relief; and
026	52	at least a portion of the surface further including an anatomical relief; and
780	1	at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface; and

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018¹

• Page 18

- Similar to generic guides, see supra II.C.2, the patient-specific guide need not match the entire surface area of the joint to provide a sufficient fit; they instead have a surface that matches portions of the joint. For example, Radermacher², describes a patient-specific guide needing only a few contact areas to achieve a patient-specific fit. Radermacher states that the "negative mold can reproduce a cohesive region or a plurality of geometrically non-abutting partial segments of a bone surface." As another example, Berez³ explains only portions of the patient's anatomy need to be matched to provide a sufficient patient-specific fit.

¹ In the following quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

² Referring to of International Pub. No. WO 93/25157

³ Referring to U.S. Patent Pub. No. 2004/0236424

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught including anatomical relief in a tool for joint arthroplasty, including, but not limited to one more relieved portions that do not engage an anatomical structure, at least under the constructions implicit in Conformis's infringement contentions. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that the use of anatomical relief can increase the accuracy of tool guide alignment and the resulting work done to the bone. Additionally, many of the Charted References taught the use of anatomical relief in tools for joint arthroplasty, including total knee arthroplasty. Thus, a person of ordinary skill in the art would have been motivated by Charted References to include an anatomical relief in a patient-specific surface.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Stone

- Paragraph [078]

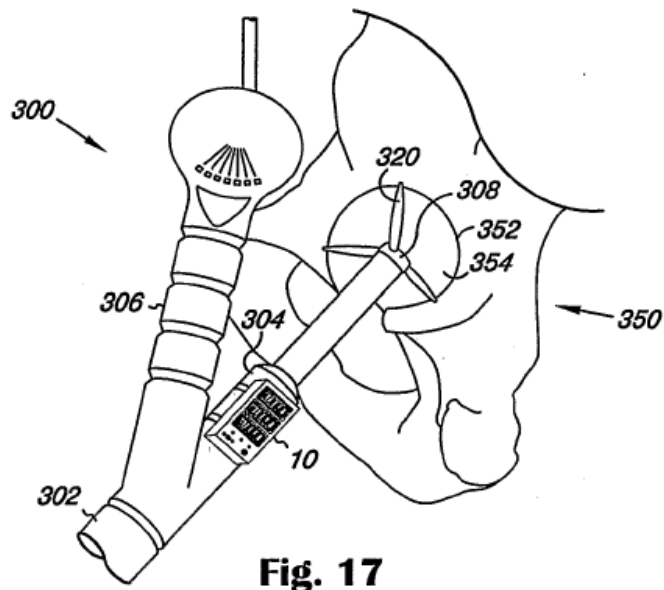
- As shown, the alignment guide 308 includes a body portion 318 and wings or arms 320a, 320b, and 320c, which are disposed generally in the same plane. The body portion 318 includes internal threads 316 for mating with the support shaft 304. In one embodiment, the arms 320 secured at points 320 degrees apart around the circumference of the body portion 318 by pivots 324a, 324b, and 324c. The pivots 324 allow for slight in-plane rotation of the arms 320 where necessary, for example to avoid contact with an anatomical aberration as the lip of the acetabulum.

- Paragraph [083]

- According to one embodiment, as described above, the arms 320 are adjusted in length by the surgeon using a telescoping action. In another embodiment, the surgeon may need to pivot the arms 320 to avoid an osteophyte or other surface aberration on the rim 352 of the acetabulum 354.

- Figure 17

-



- Paragraph [091]

- The guide 510 is placed on the rim of the glenoid, such that the upper arm is placed at the most superior position of the rim, and the anterior and posterior arms are generally aligned in the center of the superior/posterior glenoid (block 558). Again, the arms may be adjusted to avoid significant osteophytes.

- Paragraph [092]

- In yet another embodiment, the device 10 is used by a surgeon to facilitate TKA.

A person of ordinary skill in the art would have been motivated to combine the teachings of Stone with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For

example, a person of ordinary skill in the art would recognize that the teachings in Stone could be applied to templates for orthopedic interventions, such as total knee arthroplasties. *See, e.g.*, Stone at [0091] (“In yet another example, the device 10 is used by a surgeon to facilitate TKA.”). Furthermore, Stone teaches that its application to total knee arthroplasties could yield benefits, including more accurate alignment of the resection guides and ultimately an implant. *Id.* at [0091] (“For TKA, the device 10 may be affixed to the initial guides commonly used by surgeons, to enable more accurate alignment than that provided by the existing guides. In various exemplary embodiments, the device 10 can be affixed to the cutting blocks to provide more accurate rotational alignment, varus/valgus alignment, and level of resection.”). Furthermore, a person of ordinary skill in the art would have been motivated to combine the teachings of Stone with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References, as Stone taught that “[c]orrect positioning of surgical instruments and implants, used in a surgical procedure, with respect to the patient’s anatomy is often an important factor in achieving a successful outcome,” and that anatomical relief can be necessary or desirable in some situations. *See, e.g., id.* at [0002]; [0077] (“The pivots 324 allow for slight in-plane rotation of the arms 320 where necessary, for example to avoid contact with an anatomical aberration as the lip of the acetabulum.”); [0082] (“In another example, the surgeon may need to pivot the arms 320 to avoid an osteophyte or other surface aberration on the rim 352 of the acetabulum 354.”). Finally, a person of ordinary skill in the art would recognize that Stone and many of the Charted References are from the same field of invention. *Id.* at [0001] (“The present invention relates to medical orientation and positioning devices and in particular to a device for orienting surgical instruments, implements, implants, prosthetics, and anatomical structures.”).

ii. Radermacher Thesis

- Figure 4-24

-

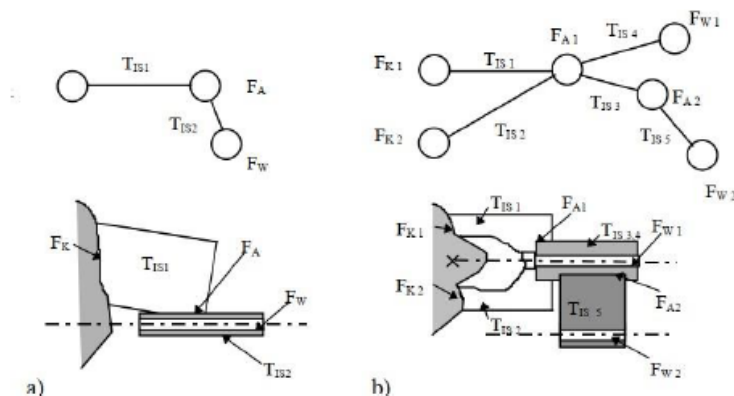


Figure 4-24: Examples of different connection structures of customized templates (cf. [Koller 1994], p. 60): a) simple customized template with one contact, alignment and tool guide surface each and template element as connection structure; b) template with several contact, alignment and tool guide surfaces; the standardized partial elements $T_{IS\ 3,4,5}$ reproduce an intrinsic processing geometry (for example, implant-specific), the functional surfaces F_{A2} , F_{W1} and F_{W2} are in this case generally not individually adapted. Individually adapted functional surfaces are F_{K1} and F_{K2} and, if required such as for alignment and positioning, F_{A1} . The shape of T_{IS1} and T_{IS2} can be standardized or adapted to individual anatomical conditions according to requirements.

- Page 90

- The general technical structure of customized templates can thus be composed of the following elements:
 - Individually adapted contact surface(s) F_{Ki} ,
 - Individually adapted or standardized adapter surfaces (F_{Ai}) for aligning the tool guides, in relation to the reference
 - Individual, but generally standardized tool guidance surfaces F_{Wi} , as well as A connection structure consisting of one or more individually adapted and/or standardized template partial elements $T_{IS\ i}$ (Figure 4-24).

- Pages 55-56

- 4.1 The concept of customized templates

The aim of the development is, on the one hand, to support the planning of surgical corrective procedures on bone structures by computer-aided preprocessing and reconstruction of three-dimensional CT image data, by linking additional information specific to the procedure or implant, and by additional tools for analysis and simulation. On the other hand, the preoperative planning information is to be stored and processed, in such a way, that intraoperative processing of the real bone structure, with conventional processing tools, is possible with corresponding accuracy.

The basic idea of the developed solution approach is to supplement the information of the exact spatial position, relative to the bone, which is missing from the conventional standard templates, based on individual CT image-based bone geometry model data, as well as the individual spatial planning of the surgeon. This is intended to exploit the advantages of conventional processing devices, to increase their accuracy, but also to create implementation aids for orthopedic procedures for which no processing devices are currently available.

Individual templates will be constructed on a patient-specific basis, using 3D reconstructions of preoperative CT image information. In addition to the surgical processing geometries, attachment areas of the template on the natural surface of the bony structure, which are conventionally accessible to the surgeon, are also defined as reference structures.

These segments of the individual bone surface geometry, reconstructed from CT data, are then structurally incorporated preoperatively into a corresponding template element under computer control, in such a way, that a clearly defined positive fit of the template, on the corresponding natural surface of the bone, is ensured and a planned position can thus be retrieved intraoperatively.* In addition, tool guides are integrated or adapted into the template elements, in position and orientation according to the planned processing geometry. . . . The solution concept is thus based on the process concept shown schematically in Figure 4-2, which is to be included in the further development and evaluation of the solution approach.

* The referencing structure of the template is referred to in the following as “contact area,” although it does not necessarily have to be a continuous area (see section 4.4.2).

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach

patient-specific templates for total knee arthroplasty. *See, e.g.*, Radermacher Thesis at 3 (“Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen.”). Furthermore, Radermacher Thesis teaches that the disclosed individual templating technique can be applied to total knee arthroplasty. *See, e.g.*, Figure 4-37. Thus, a POSITA would be motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References.

C. “Subchondral Bone” Limitations

Accommodating and/or conforming to a subchondral bone surface, including as recited in the following Asserted Claims, was well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff’s infringement contentions:

Patent	Claim	Claim Language
026	23	The system of claim 15, wherein said anatomic relief accommodates an area of subchondral bone on the first articular surface of the joint.
304	4	The surgical instrument of claim 1, wherein the internal surface substantially conforms to the shape of a surface of the joint of the patient, wherein the surface of the joint includes a cartilage surface of the joint and a subchondral bone surface of the joint.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art
 - i. Asserted Patents

- '745 Patent, 2:66-3:11; '482 Patent, 3:8-21; '161 Patent, 3:7-19; '129 Patent, 2:35-47; '304 Patent, 2:35-47; '026 Patent, 2:51-63; '780 Patent, 2:51-63
 - Usually, severe damage or loss of cartilage is treated by replacement of the joint with a prosthetic material, for example, silicone, e.g. for cosmetic repairs, or metal alloys. See, e.g., U.S. Pat. No. 6,383,228 to Schmotzer, issued May 7, 2002; U.S. Pat. No. 6,203,576 to Afriat et al., issued Mar. 20, 2001; U.S. Pat. No. 6,126,690 to Ateshian, et al., issued Oct. 3, 2000. Implantation of these prosthetic devices is usually associated with loss of underlying tissue and bone without recovery of the full function allowed by the original cartilage and, with some devices, serious long-term complications associated with the loss of significant amount of tissue and bone can include infection, osteolysis and also loosening of the implant.
- ii. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018⁴
- Pages 5-6
 - Damage to the knee joint can occur by acute trauma or through chronic degeneration. Osteoarthritis is a common example of chronic cartilage degeneration. And because cartilage has a limited ability to repair itself, cartilage damage can be quite detrimental. Under even normal use, articular cartilage can soften and wear away, reducing lubrication, disrupting normal load transfer, and making articulation more difficult. It is relatively common for articular cartilage to completely wear away (at least in some areas), exposing the underlying subchondral bone. This typically occurs on both femoral and tibial aspects of the knee joint and leads to bone-on-bone articulation between the distal end of the femur and the proximal end of the tibia. This can be quite painful and leads to joint inflammation and reduced function.

Cartilage degeneration is often categorized into five grades based on degree or severity of damage. The first, "Grade 0," is assigned to healthy articular cartilage. "Grade 1" is assigned to articular cartilage that has started to swell and soften. This may be in response to normal wear or a localized injury. "Grade 2" is assigned to cartilage with a "partial-thickness (less than 50%) defect with fissures, ulceration, and fibrillation on the surface." "Grade 3" is assigned to cartilage with a "partial-thickness (greater than 50%) defect with fissures, ulceration, and fibrillation on the surface." And "Grade 4," the most severe, is assigned to cartilage with a "full thickness (100%) defect with exposed subchondral bone (bone-on-bone)." With every increase in the degree of cartilage damage, available means of treatment and repair become more drastic. Once "Grade 4" damage is realized, the only solution is usually a total knee replacement procedure, or "total knee arthroplasty."

⁴ In the quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

- Page 8

- When cartilage damage or degeneration is severe, e.g., from osteoarthritis, the articular cartilage is completely gone (in at least some areas) and the exposed bone surfaces of the femur and tibia contact and rub against one another. The patient experiences pain; stiffness; creaking or grating upon articulation; and instability, including buckling and locking of the knee. In addition, the knee joint is deformed, in either a varus or valgus misalignment. Once a patient has reached this level of degradation, a total knee arthroplasty is often the only solution to relieve pain and restore function. Total knee arthroplasty is aggressive and highly invasive, and it involves, regardless of the type of implant or surgical tool used, the resection of a portion of the femur and tibia and replacing it with an implant.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught an area accommodating and/or conforming to an area of subchondral bone. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that accommodating and/or conforming to an area of subchondral bone can increase the accuracy of tool guide alignment and the resulting work done to the bone. Furthermore, many of the Charted References taught accommodating and/or conforming to an area of subchondral bone in tools for joint arthroplasty, including total knee arthroplasty. Thus, a person of ordinary skill in the art would have been motivated by Charted References to have a surface accommodating and/or conforming to an area of subchondral bone on a tool for joint arthroplasty.

3. Additional References

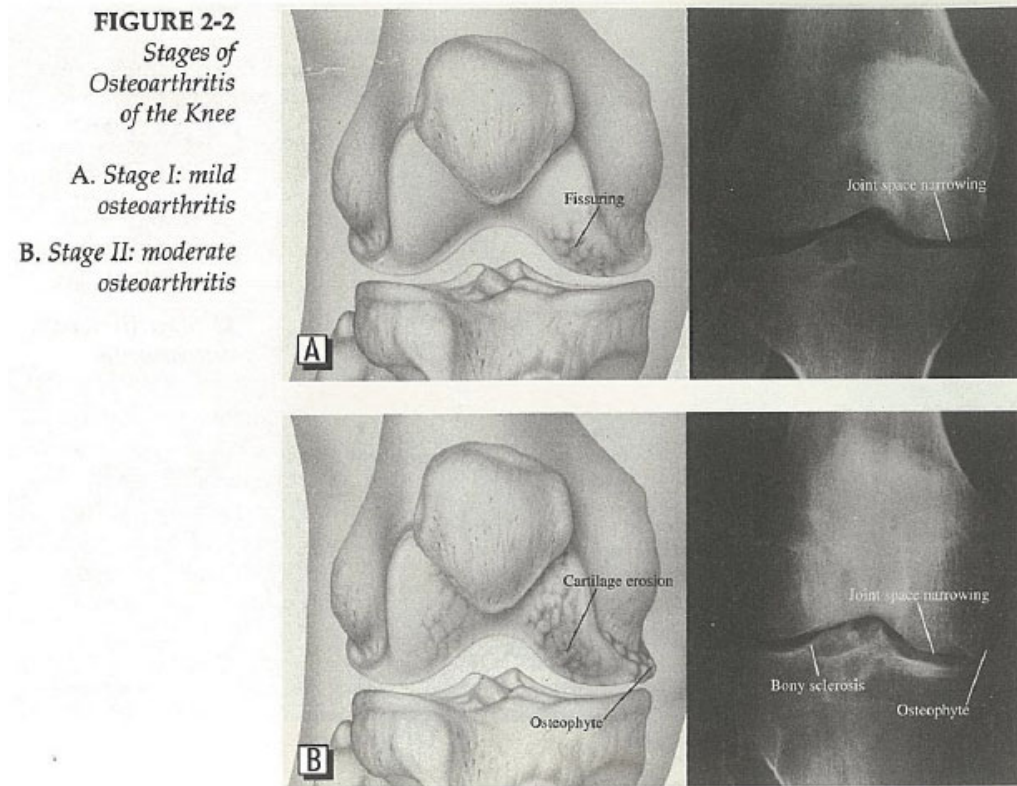
The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. ARTHRITIS OF THE HIP & KNEE

- Pages 12
 - Osteoarthritis is an abnormal condition that causes a joint and its surrounding structures to deteriorate to varying degrees. (See Figures 2-1 and 2-2 on the stages osteoarthritis of the hip and knee.) This degeneration in turn may cause pain and loss of function, also to varying degrees.
- Pages 13-14
 - Arthritis creates abnormalities within the structure of the joint. These abnormalities can cause the soft tissue that can cause the firm, smooth, shiny surface of the joint (the articular cartilage) to become thin and irregular. The bone under the cartilage may become very dense and stiff. Outgrowths, called osteophytes or spurs, may appear at the edge of the articular cartilage. These abnormalities within the joint cause weakness of the muscles and surrounding ligaments, joint instability, and pain.

- Figure 2-2

○



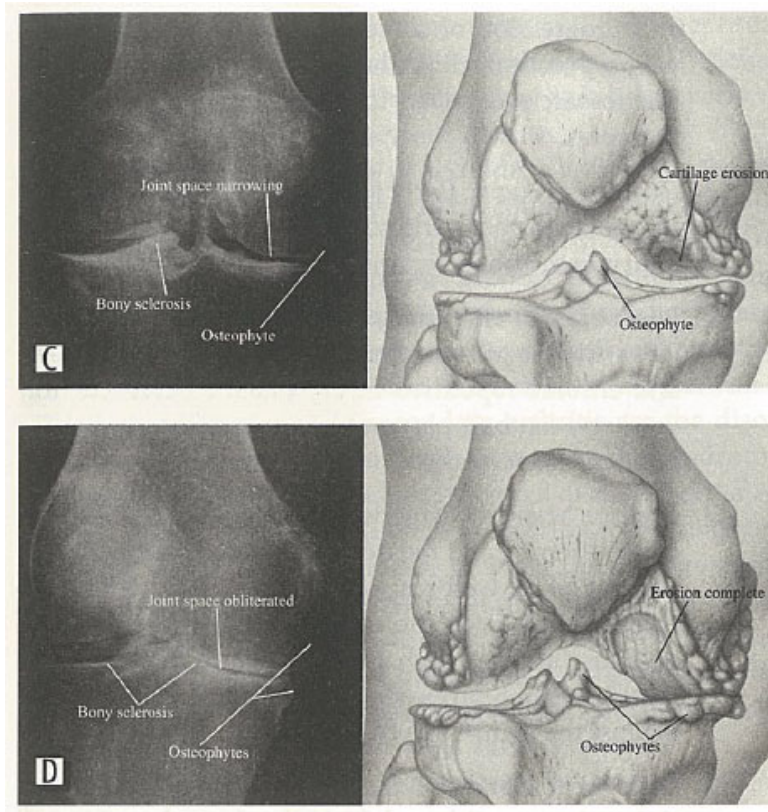


FIGURE 2-2

*C. Stage III:
moderately severe
osteoarthritis*

*D. Stage IV: severe
osteoarthritis*

- Figure 2-1

○

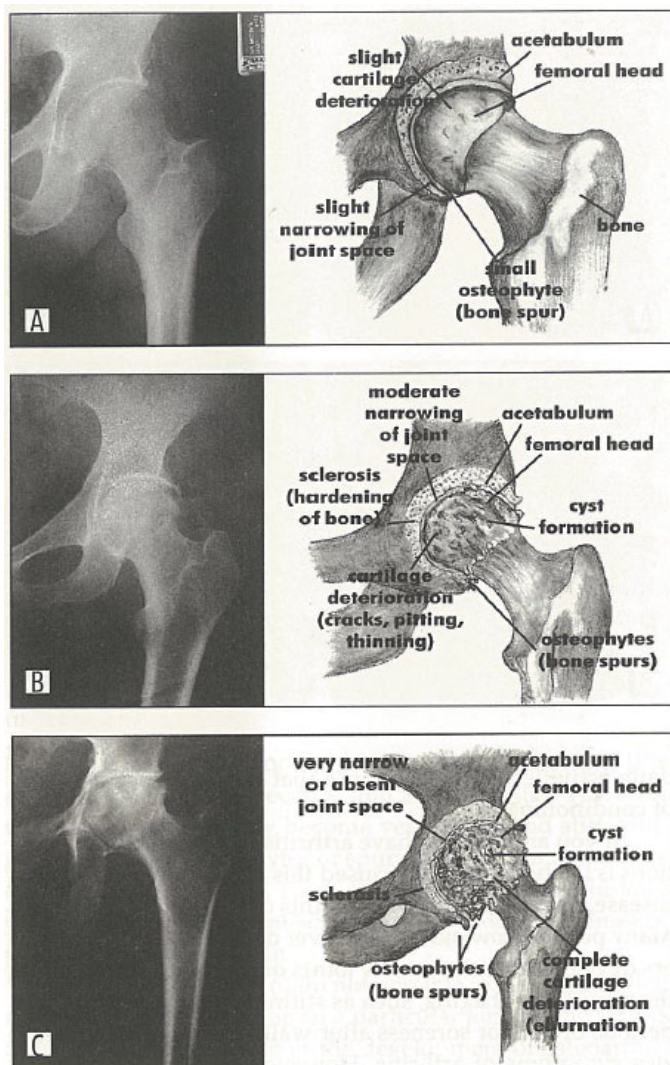


FIGURE 2-1
Stages of
Osteoarthritis
of the Hip

A. Stage I: mild
osteoarthritis

B. Stage II: moderate
osteoarthritis

C. Stage III: severe
osteoarthritis

- Page 63

- Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful.

A person of ordinary skill in the art would have been motivated to combine the teachings of ARTHRITIS OF THE HIP & KNEE with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that ARTHRITIS OF THE HIP & KNEE teaches the anatomical conditions of a joint with osteoarthritis. Specifically, ARTHRITIS OF THE HIP & KNEE teaches that in the advanced stages of osteoarthritis, which is when it is most often clinically indicated for patients to undergo total knee arthroplasty, there is exposed subchondral bone on the articular surfaces of the knee. *See, e.g.*, Figure 2-2; Page 63 ("Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful."). Many of the references identified in Defendants' Invalidity Contentions are directed to tools for total joint arthroplasty, including total knee arthroplasty. These references teach generally the advantages of considering a patient's joint anatomy when designing surgical guides/templates/molds. Thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint arthroplasty, including the presence of exposed subchondral bone, into account when designing the total joint arthroplasty tool and accommodate the exposed subchondral bone.

- ii. OSTEOARTHRITIS HANDBOOK

- Pages 36-37

- There are many ways in which osteoarthritis begins. Abnormal stress on the cartilage is a major suspect. Scientists are investigating how these disease-initiating stresses differ from the constant, everyday compression, oscillation, twisting, and turning to which cartilage is subjected. Damage to other structures of the joint, such as the ligaments or tendons, may result in abnormal loading of the cartilage and lead to osteoarthritis. . . .

The chondrocytes attempt an unsuccessful repair. There may be bone spur formation or bony overgrowth, both of which aggravate the condition, further impairing motion. Once initiated, the disease process is aggravated because articular cartilage cannot easily repair itself.

This trauma to the cartilage causes a disorganization of the collagen network and promotes water retention. These changes may initiate the disease process. The smooth cartilage surface may become pitted and frayed. Eventually the cartilage may lose some of its ability to hold fluid, thereby becoming less able to withstand loading. This irregular joint surface may begin to interfere with smooth joint movement. . . .

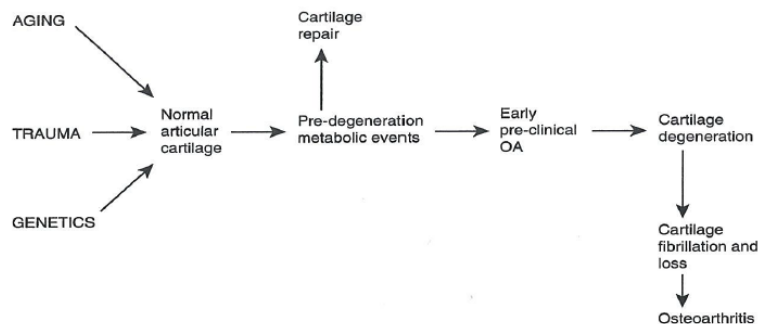
As the disease progresses, more cartilage breaks down. The joint space narrows, and eventually, instead of effortlessly gliding over one another, bones rub on uncushioned bones, making joint motion excruciatingly painful and often totally impossible. Fortunately it usually takes many years for the process to become noticeable or to interfere with a pleasurable lifestyle.

Because osteoarthritis involves deterioration of the cartilage, the disease is often called degenerative joint disease, or DJD. Figure 3-5 schematizes the vicious cycle characteristic of osteoarthritis.

- Figure 3-5

○

FIGURE 3-5: *The Progressive Development of Osteoarthritis*



The initiating factor for osteoarthritis may be one of many things, including trauma, aging, or genetic predisposition. There is an initial breakdown of the extra-cellular matrix, to which the chondrocytes will respond. These cells will attempt to repair the damaged cartilage, and the repair may be successful. The attempts at repair may, however, be unsuccessful, and the incremental breakdown will become overwhelming. Ultimately the cartilage will undergo dramatic degeneration leading to osteoarthritis. These events may occur over many years.

- Page 153

- **Moderate Osteoarthritis**

Progressively, osteoarthritis destroys the delicate architecture and function of the knee joint. The cartilage covering the ends of the tibia and femur wears away. The joint space narrows.

- **Severe Osteoarthritis**

When the entire hyaline cartilage is gone and the joint space has vanished, bone rubs on bone, and any movement is excruciatingly painful. Large bone spurs, or osteophytes, may grow along the periphery of the joint. These spurs can be seen as the body's attempt to increase the area available for load bearing. They may also be the body's attempt to stiffen up the joint since less movement often means less pain. Depending on their location, these spurs can actually increase the pain.

Osteoarthritic damage is often limited to the destruction of the hyaline cartilage and the formation of bony overgrowths. There can also be a marked shortening of the tendons and ligaments, which makes it impossible for the patient to completely straighten the knee (flexion contracture).

- Page 195-196

- Diagnosis is complicated since the shoulder develops many aches and pains, most of them not related to arthritis. . . .

An X ray confirms a diagnosis. Early osteoarthritis is marked by joint space narrowing. As the disease progresses, the smooth hyaline surface is pitted, becoming increasingly uneven. More advanced disease is characterized by osteophyte formation. Eventually the shoulder cartilage wears out, and bone rubs on bone. (See Chapter 3 for more on the development of OA.)

A person of ordinary skill in the art would have been motivated to combine the teachings of OSTEOARTHRITIS HANDBOOK with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that OSTEOARTHRITIS HANDBOOK teaches that there can be exposed subchondral bone in the advanced stages of osteoarthritis, which is when it is most often clinically indicated for patients to undergo total knee arthroplasty. *See, e.g.*, Page 37 ("As the disease progresses, more cartilage breaks down. The joint space narrows, and eventually, instead of effortlessly gliding over one another, bones rub on uncushioned bones, making joint motion excruciatingly painful and often totally impossible."). Further, many of the references identified in Defendants' Invalidity Contentions are directed to tools for total joint arthroplasty, including total knee arthroplasty. These references teach generally the advantages of considering a patient's joint anatomy when designing surgical guides/templates/molds. Thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint arthroplasty, including the presence of exposed subchondral bone, into account when designing patient-specific tools for total joint arthroplasty.

iii. Alexander

- Pages 14-15

- MRI, with its superior soft tissue contrast, is the best technique available for assessing tissue and its defects, for example articular cartilage and cartilage lesions, to obtain a cartilage degeneration can provide morphologic information about the area of damage. Specifically, changes such as fissuring, partial or full thickness cartilage loss, and signal changes within residual cartilage can be detected.

The reason MR imaging techniques are particularly suitable for cartilage is because they can provide accurate assessment of cartilage thickness, demonstrate internal cartilage signal changes, evaluate the subchondral bone for signal abnormalities, and demonstrate morphologic changes of the cartilage surface.

MRI provides several important advantages over other techniques in this invention. One advantage is good contrast between cartilage, bone, joint fluid, ligaments, and muscle in order to facilitate the delineation and segmentation of the data sets. Another is the coverage of the entire region of interest in a single scan within acceptable acquisition times.

- Page 40
 - Since the algorithm for 3D surface registration of the femoral condyles also computes the surface normals for the medial and lateral femoral condyles on a pixel-by-pixel basis, it can form the basis for developing maps of cartilage thickness. Fig. 11 shows an example of a 2D map of cartilage thickness derived from the surface normals of the lateral femoral condyle. Figure 11A shows a proton density fast spin-echo MR image that demonstrates a focal cartilage defect in the posterior lateral femoral condyle (black arrows). White arrows indicate endpoints of thickness map. Figure 11 B is a 2D cartilage thickness map that demonstrates abrupt decrease in cartilage thickness in the area of the defect (arrows). The Δ thickness between neighboring pixels can be used to define the borders of the cartilage defect. Note diffuse cartilage thinning in area enclosed by the astericks (*).
- Page 61
 - An example of this type of visualization is given in Figure 18. The Figure shows what can be referred to as functional joint imaging. Figure 18A is a photograph demonstrating the position of the external markers positioned around the knee joint. The markers are filled with dilute Gd-solution. B is Sagittal 3D SPGR image through the medial femorotibial compartment. Two of the external markers are seen anteriorly as rounded structures with high signal intensity. C is 3D reconstruction of femoral and tibial bones (light grey), external 20 markers (dark grey), femoral cartilage (red), and tibial cartilage (blue) based on the original SPGR MR images.

- Figure 18C

-



A person of ordinary skill in the art would have been motivated to combine the teachings of Alexander with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Alexander teaches that the imaging techniques taught in the Alexander are "particularly useful for assessing synovial joints, particularly the knee" and that MRI can image subchondral bone. *See, e.g.*, Alexander at 14, Figure 18C; *see also id.* at 14 ("The reason MR imaging techniques are particularly suitable for cartilage is because they can provide accurate assessment of cartilage thickness, demonstrate internal cartilage signal changes, evaluate the subchondral bone for signal abnormalities, and demonstrate morphologic changes of the cartilage surface."). Thus, a person of ordinary skill in the art would understand that subchondral bones would likely be present on joint surfaces and should be accounted for. Furthermore, many of the Defendants' Identified References disclose tools for total knee arthroplasty, and specifically patient-specific tools for total knee arthroplasty with patient-specific surfaces constructed from image data that correspond to areas of the knee where subchondral bone can be present. Thus, given that Alexander teaches MRI can image subchondral bone, it would be obvious to a POSITA to apply the imaging techniques taught in Alexander to construct a patient-specific surface and include the subchondral bone information from the MRI in the patient-specific surface. This is because, *inter alia*, many of the Defendants' Identified References teach generally the advantages of considering a patient's joint anatomy when designing surgical guides/templates/molds. Thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint

arthroplasty, including the presence of exposed subchondral bone, into account when designing the total joint arthroplasty tool and accommodate the exposed subchondral bone.

iv. Insall

- Page 22

- Examination of gross specimens or arthroscopic visualization reveals normal cartilage to be a white, smooth, and firm material. Articular cartilage damage or degeneration, termed chondromalacia, can be quite readily identified (Fig. 2.14). These characteristic changes seen during arthroscopic examination have been classified by Outerbridge⁶⁴: grade 0 is normal, white-appearing cartilage; grade I is swelling or softening of an intact cartilage surface; grade II is represented by fissuring and fibrillation over a small area (<0.3 inch); grade III is the same pathological changes over a larger area (>0.5 inch); grade IV changes represent erosion to the subchondral bone and are indistinguishable from osteoarthritis. Chondral flap tears caused by delamination of the articular cartilage may also be encountered (Fig. 2.15).

- Figure 2.15

○



FIGURE 2.15 ➤ Arthroscopic views of articular cartilage. Normal white, smooth articular cartilage (Outerbridge grade 0) in the medial (A), lateral (B), and patellofemoral compartments (C and D). Softening of the articular surface of the lateral tibial plateau (E) and patellofemoral articulation (F) with indentation at the probe tip (Outerbridge grade 1) is noted. (G) A small fissure and fibrillation of the medial femoral condyle (Outerbridge grade 2). Extensive fibrillation of the articular cartilage involving the tibial plateau (H) and patella (I) (Outerbridge grade 3). Erosion of articular cartilage to subchondral bone involving the medial femoral condyle (J) and patella (K) (Outerbridge grade 4). Arthroscopic view of a chondral flap tear (L); the probe tip is deep to a flap of delaminated articular cartilage on the medial femoral condyle.

- Page 22

- These changes in the articular cartilage cannot be directly visualized on conventional radiographs but may be seen on magnetic resonance imaging (MRI) studies. However, even MRI is unreliable for detecting early stages of chondromalacia.

These may appear as foci or areas of diffuse abnormal signal with a normal surface. Grade III or IV chondromalacia is visible as thinning, irregularity, and fissuring of the cartilage (Fig. 2.16).

- Figure 2.16

○



FIGURE 2.16 > A Axial magnetic resonance imaging (MRI) shows normal articular cartilage (a) on the patella facets. The cartilage has a uniform signal thickness and appearance. B, Axial MRI reveals fissuring and fibrillation of articular cartilage on the medial facet of the patella (arrow). C, Axial MRI with advanced chondromalacia of the patella. The signal irregularity extends to the subchondral bone, and a deep fissure is identified (arrow). D, Coronal MRI demonstrates complete loss of the articular cartilage of the medial compartment (thin arrows). For comparison, the gray band of articular cartilage on the lateral tibial plateau is also identified (thick band).

A person of ordinary skill in the art would have been motivated to combine the teachings of Insall with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Insall and many of the identified references come from the same field,

i.e., knee surgery, and that Insall is focused on communicating relevant information regarding knee surgery. A POSITA would also recognize that Insall teaches the anatomical conditions of the knee that should be taken into account when conducting knee surgery. Specifically, Insall teaches that when damage occurs to articular cartilage on the knee, subchondral bone can be exposed. Many of the Defendants' Identified References teach generally the advantages of considering a patient's joint anatomy when designing surgical guides/templates/molds. Thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint arthroplasty, including the presence of exposed subchondral bone, into account when designing the total joint arthroplasty tool and accommodate the exposed subchondral bone.

D. "Guide" Limitations

Guides for a tool, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
026	15	at least one guide for directing movement of a surgical instrument; and
026	16	The system of claim 15, wherein the at least one guide includes at least one of the features selected from the group of features consisting of a guide aperture, a reaming aperture, a drill aperture, a cutting slot, and a cutting plane.
026	52	at least one guide for directing movement of a surgical instrument; and
129	1	a guide for directing a surgical instrument,
482	1	a guide sized and shaped to accommodate a surgical tool,
482	17	a block having a patient-specific surface and a guide:
482	17	the guide being sized and shaped to accommodate a surgical tool and
745	1	a guide configured to accommodate a surgical tool for cutting or drilling tissue;
780	1	at least one guide for directing movement of a surgical instrument; and
780	3	moving the surgical instrument with the at least one guide to prepare the joint of the patient for receiving an implant.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Asserted Patents

- '745 Patent, 69:11-15; '482 Patent, 69:19-23; '161 Patent, 69:20-24; '129 Patent, 43-65-44:2; '304 Patent, 44:3-7; '026 Patent, 52:59-63; '780 Patent, 6-10
 - Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee.
- '745 Patent, 97:57-61; '482 Patent, 98:1-5; '161 Patent, 98:1-5; '026 Patent, 80:65-81:2; '780 Patent, 81:10-14
 - For example, a standard surgical cut block as described for standard implants, for example in the knee the J&J PFC Sigma system, the Zimmer Nexgen system or the Stryker Duracon system, can be connected or placed on the mold.

ii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

- Paragraph 44
 - As I mentioned above, knee arthroplasty techniques have changed very little since the introduction of intramedullary and extramedullary rods. Improvements have instead been made to the orthopedic implant components themselves; for example, improvements have been made to their shape and material. Improvements have also been made to the cutting guides themselves. For example, the early cutting guides utilized open cutting planes, and because open planes are not confined, saws were prone to slipping off of the cutting planes. As a result, cutting slots were developed. These slots have been further refined to increase the precision of the resulting resections.
- Paragraph 60
 - *Berez* describes patient-specific cutting guides for use in joint arthroplasty procedures. Ex.B at Title, Abstract; *see also id.* ¶¶ [0265]-[033 l]. The cutting guides have a surface that will match a portion of an articular or a bone surface. *Id.* ¶ [0266]. The guides also have apertures, slots, and/or holes to accommodate surgical tools such as saws and drills. *Id.* *Berez* explains that "[t]ypically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general [cutting

guide] orientation for subsequent placement of an articular repair system [(implant)] or for facilitating placement of the articular repair system [(implant)]." *Id.* ¶ [0267].

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught guides to accommodate and/or direct the movement of a tool. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that tool guides can increase accuracy and efficiency in surgery, including specifically in knee surgery. Furthermore, the Charted References taught the use of design considerations such as individualized and/or standard/reusable guides with the specific types and number of apertures being selected depending on the type of surgery being performed, manufacturing consideration, etc. Thus, a person of ordinary skill in the art would have been motivated by the Charted References to include one or more guides in a patient-specific instrument to yield the predictable benefit of a design suited for the particular surgery being performed.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Krackow

- Page 163

- **Cutting Guides**

- With increased attention to achieving alignment accuracy and especially with the trend in press-fit uncemented arthroplasty, interest in precision bone cutting and bone surface preparation has increased. Instrumentation systems use at least three mechanisms for preparing bone surfaces; these include cutting slots, cutting surfaces, and rotating planing instruments. One needs to be aware of the pitfalls and advantages of each.

- Page 163-165

- **Slots**

Cutting slots appear to be the most readily accepted or desired cutting guides. They restrict the angular deviation of a saw blade and provide the surgeon with a sense of security in regard to accuracy. Certain cautions, however, are necessary if one is to avoid problems with their use (Figure 5-27). Cutting slots cannot rigidly guide or absolutely direct a saw blade. This statement is based on two considerations. From a practical standpoint, there needs to be some free space between the borders of the cutting slot and the saw blade if the blade is to move without binding. Even a fraction of a millimeter of play can allow significant angular variation in the course of the blade. When this fact is added to the consideration that even within a given blade manufacturer's products there are varying thicknesses of blades, the possibility of having even greater play in the system is quite real. The surgeon could try to assure himself that he uses blades of a thickness optimally matched to the size of his cutting slot. Certainly, this would minimize one source of error. On the other hand, as covered in the section on saw technique (Chapter 7), such may well represent an undesired restriction; i.e., many times a thicker or thinner saw blade may be more appropriate. If, however, the slot is matched for the thinnest of saw blades at the beginning, then we have magnified to its greatest potential the second problem that must be considered—the tendency for blades to bend or skive away from hard bone. A blade that is tightly guided or trapped by a cutting slot is otherwise uncontrollable when such skiving occurs. In this case the slot makes it impossible for the surgeon to lean into the blade to protect against such skiving.

One simply needs to be aware of these limitations concerning cutting slots, especially since they block one's view of the blade in assessing its exact position against the jig. The slots, in general, do provide some boundary to the range of cutting error and, especially for performing cemented arthroplasty, these bounds may be quite acceptable.

Recently a rather ingenious type of cutting slot has been introduced. This slot is offset in a manner that permits a forceful leaning type of maneuver so that functionally it appears that the slot is being made appropriately thin to match the dimensions of the saw blade being used. In reality, we have with this system a functionally deeper and possibly thinner cutting slot (Figure 5-28). The arrangement addresses certain problems of the standard cutting slot, namely, the difficulties involved in inserting a relatively thick blade through a tight slot. The angular error caused by excess thickness of the cutting slot has been minimized. However, a small angular difference for thick and thin blades must still exist, and the problem of trying to exert greater antibending, antiskiving force still persists. In addition, the configuration of such an instrument limits the amount of intrusion that the saw blade can make into the bone or, conversely, requires a longer saw blade, which is a relatively less efficient cutter and over which one has less bending control. Attention to detail is still required even with this clever approach.

- Figure 5-27

○

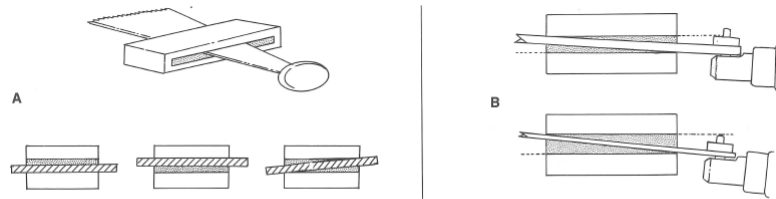


FIGURE 5-27

A, Saw blade protruding through cutting slot. Saw blade may rest either along one surface or other of slot or may be tilted one direction or other, depending on relative dimensions of saw blade in slot. **B**, Amount of angular "play" possible is less if thicker blade is used compared to thinner blade.

- Figure 5-28

-

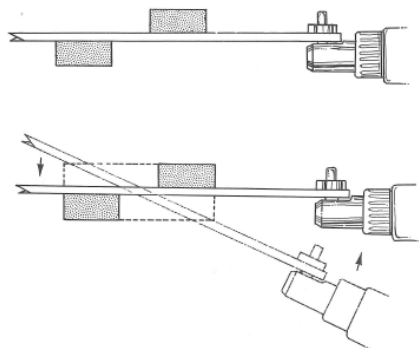


FIGURE 5-28

"Offset" cutting slot. Recent introduction into total knee instrumentation represents extended cutting slot, which is easier to position saw blade through. Potential for small degree of angular change in position depending on thickness of saw blade. This instrumentation offers certain advantages, although it blocks access of saw to bone because of relative size, that is, it is extended slot, making it more difficult to get saw close to bone or deeper into bone. To extent that offset pieces are close together and effect is minimized, then effects of changes in thickness of saw blade lead to greater positional changes in orientation of cutting edge. As with any slot technique, amount of bending force may be limited to keep blade from skiving.

- Page 165

- **Cutting Block**

Another general type of cutting guide is the cutting block or cutting surface. This device has the obvious disadvantages of exercising no external control on the direction of the saw blade; it is truly a guide only. One is free to cut too deeply or too shallow by raising or lowering the saw. The cutting guide, on the other hand, has no problems of saw blade binding; and the surgeon should not tend to have a false sense of security. It allows good visibility for assessing the blade's position, and it allows control of any skiving tendency, because one can lean as hard as one wants into the blade to resist this. Furthermore, it allows easy assessment of the accuracy of a cut that has been made. There is, however, the overriding caution that one is totally free to make rather large errors if he is not careful.

An additional consideration arising in some systems today is the removable and potentially adjustable cutting slot. This may allow the surgeon to select his preference between slot or cutting surface. In addition, if the cutting slot is adjustable, it may address many questions of blade thickness variation.

A person of ordinary skill in the art would have been motivated to combine the teachings of Krackow with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Krackow teaches that a saw slot is one of a small number of design choices, and that a saw slot can lead to increased accuracy of the cut and better alignment of the implant. *See, e.g.*, Krackow at 163 ("Cutting slots appear to be the most readily accepted or desired cutting guides. They restrict the angular deviation of a saw blade and provide the surgeon with a sense of security in regard to accuracy."); 164 ("The slots, in general, do provide some boundary to the range of cutting error and, especially for performing cemented arthroplasty, these bounds may be quite acceptable."). Furthermore, Krackow discusses the use of saw slots for total knee arthroplasty. Many of the identified references in the Defendants' Invalidity Contentions disclose templates for use in total knee arthroplasty. Thus, to the extent not already disclosed, a POSITA would have been motivated to try to use a saw slot for surgeries that use a saw to yield the predictable benefit of a design suited for the particular surgery being performed.

ii. Vomlehn

- [0038]
 - In an optional embodiment, user 3 also may use a pointing device of user interface 17 to select a position and orientation (pose) which in a surgical instrument 40 is positioned in order to correctly insert the screw or pin. Design device 25 or graphics engine 21 may have a computer model of surgical instrument 40 pre-stored, and superimpose this model upon the images provided on monitor 23.
- [0040]
 - The final pose of surgical instrument may be used to construct a guide hole 31. Guide hole 31 allows is a shaft 41 of medical equipment, such as a surgical drill 40, to fit through snugly with little clearance, intended to restrain motion of the drill 40 along in all directions except along an axis of guide hole 31 .

- Figure 2

○

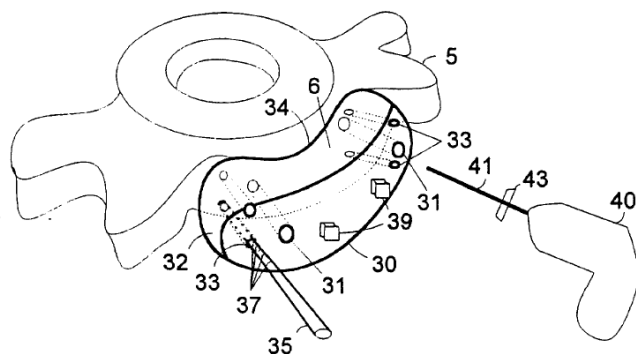


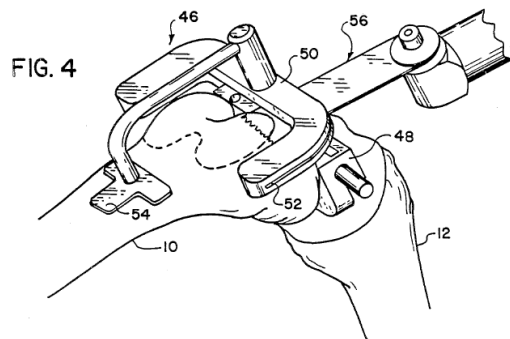
Fig. 2

A person of ordinary skill in the art would have been motivated to combine the teachings of Vomlehn with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the teachings in Vomlehn could be applied to a wide variety of orthopedic procedure, including total knee arthroplasty. *See, e.g.*, [0001] ("The present invention relates to computer-aided construction of a reference structure to be attached to a subject and act as a guide in medical procedures."); [0002] ("In various medical procedures, it is necessary to attach a piece of medical equipment into a solid structure of the subject."). Furthermore, Vomlehn teaches that the use of a tool guide in a patient-specific template can increase the accuracy of medical procedures and eliminate estimation by surgeons or the use of intraoperative imaging. *See, e.g.*, [0006] ("Typically, these pins or screws have been inserted by a surgeon who visually, or by 'feel', finds the approximate location where the screw or pin should be entered, and drills a hole at that location. The screw or pin is inserted into the hole."); [0007] ("Sometimes, during surgery, two dimensional (2D) snapshots such as x-rays or magnetic resonance (MR) images may be obtained"); [0013]-[0014] ("Currently there is a need for a device which may be attached to a subject and act as a reference structure to guide instruments during medical procedures. The present invention constructs a reference structure intended to be attached to a solid anchor site of a subject."). Thus, to the extent not disclosed, a POSITA would be motivated to include a guide for a tool in a patient-specific template.

iii. Woolson

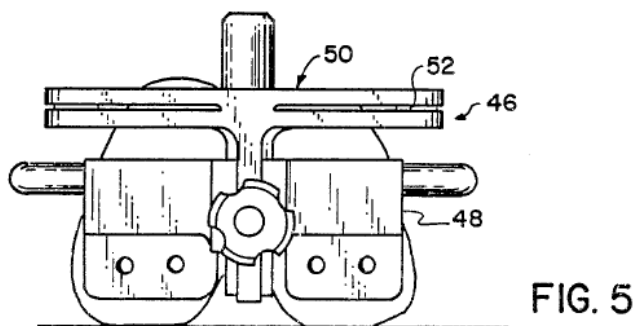
- Column 3, lines 32-33; Figure 4

- FIG 4 is a perspective view of an anterior femoral cutting guide in place on a distal femur;



- Column 3, lines 34-35; Figure 5

- FIG 5 is a distal end view of the cutting guide of FIG. 4



- Column 3, lines 36-38; Figures 6A-6B
 - FIGS. 6A, 6B are anterior and lateral views, respectively, of a femur with a distal femoral cutting guide in place

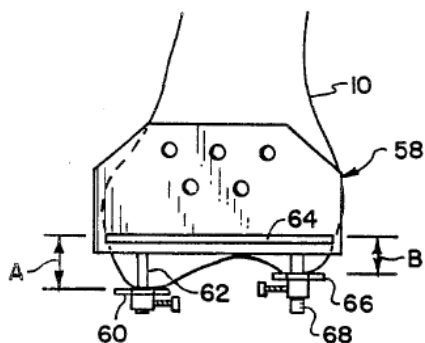


FIG. 6A

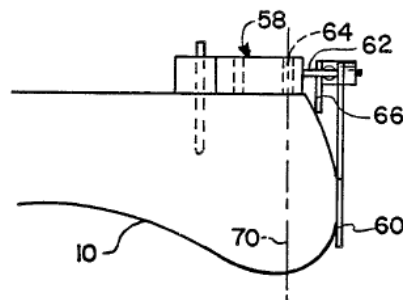
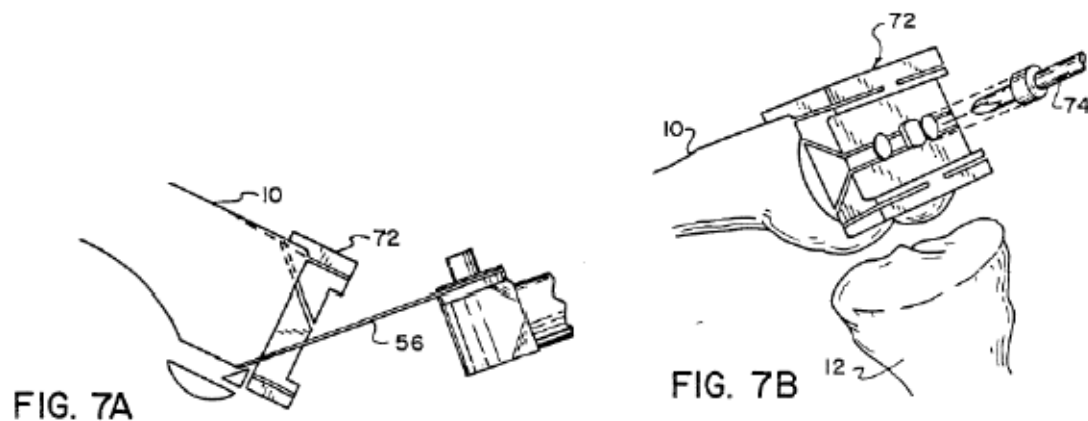
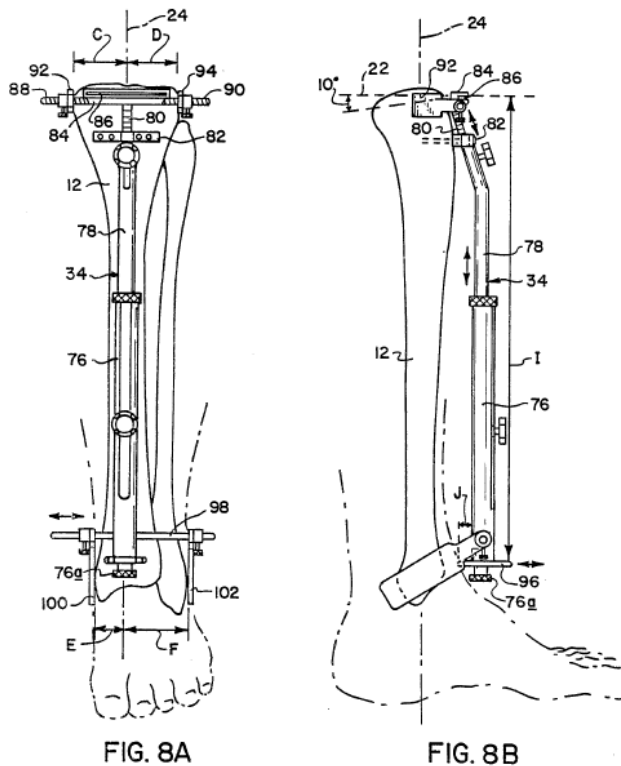


FIG. 6B

- Column 3, lines 39-40; Figures 7A and 7B (as confirmed by the PTAB in IPR2017-00372, Paper 7, Page 9)
 - FIGS 7A, 7B are a lateral view and perspective of another cutting guide for making final femoral cuts



- Column 3, lines 41-46; Figures 8A and 8B
 - FIGS 8A, 8B show anterior and lateral views, respectively, of a proximal tibial cutting guide in position adjacent a tibia showing adjustments and placement of the cutting guide for use during a knee replacement operation performed according to the present invention.



A person of ordinary skill in the art would have been motivated to combine the teachings of Woolson with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Woolson comes from the same field of invention as many of the references identified in the Defendants' Invalidity Contentions and teaches tools for total knee arthroplasty similar to many of the references identified in the Defendants' Invalidity Contentions. Additionally, Woolson teaches that proper alignment of a prosthesis relative to a mechanical axis is a factor in the long-term result of a total knee arthroplasty and discloses that its tools help achieve such alignment. *See, e.g.*, Woolson at 1:26-36 ("One of the most important causes for failure of the procedure is from prosthesis component loosening because of unbalanced loading of the tibial component caused by improper knee joint alignment. Because of this fact, all total knee implantation systems attempt

to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result.”). Thus, to the extent not already disclosed, a POSITA would be motivated to combine the teachings of Woolson with any of the references identified in Defendants’ Invalidity Contentions and to try to use a saw slot.

iv. PFC Sigma System (DPY_00009219 to DPY_00009477)

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 3

○

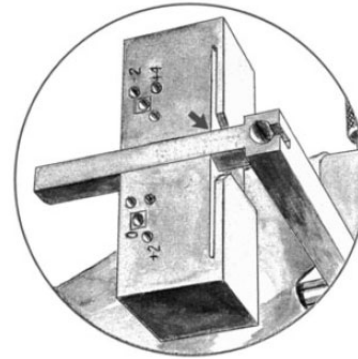
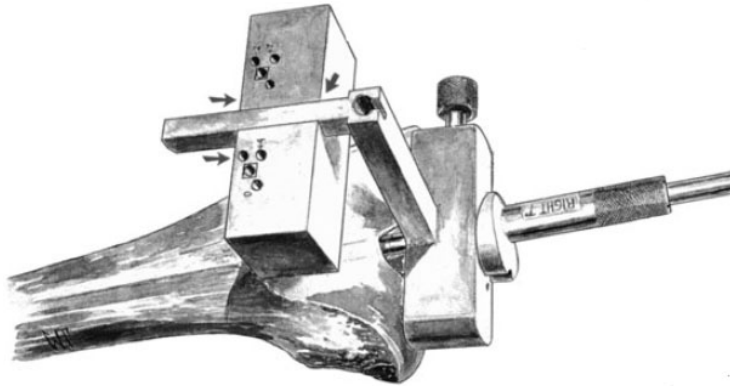
INSTRUMENTATION RATIONALE

SPECIALIST® instrumentation was designed to meet the requirements of all total-knee replacement procedures, to fully assure precise and dependable resection of the recipient bone and to serve a variety of surgical options. The instruments may be customized to meet any special requirements of the individual surgeon.

Preparation may be initiated at either the femur or the tibia. The instruments may be employed with either the intra- or extramedullary alignment approach. Bone resection is made at the appropriate level as determined through calibrated stylus assembly. A selection is offered of slotted and surface-cutting blocks. Spacer blocks are provided for extension and flexion gap evaluation.

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 12

○

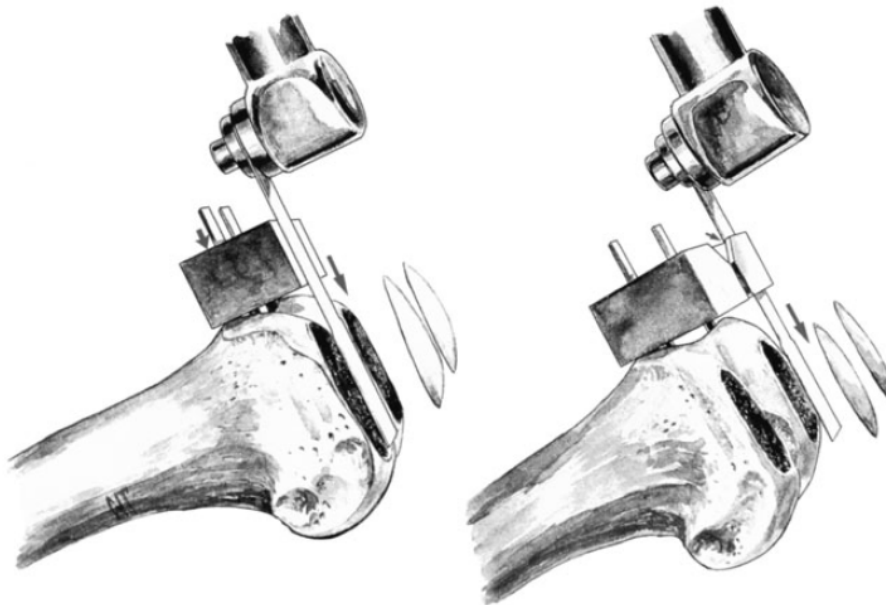


Alternatively, the cutting block is available in a slotted version. A 1.19 mm saw blade is recommended.

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 13

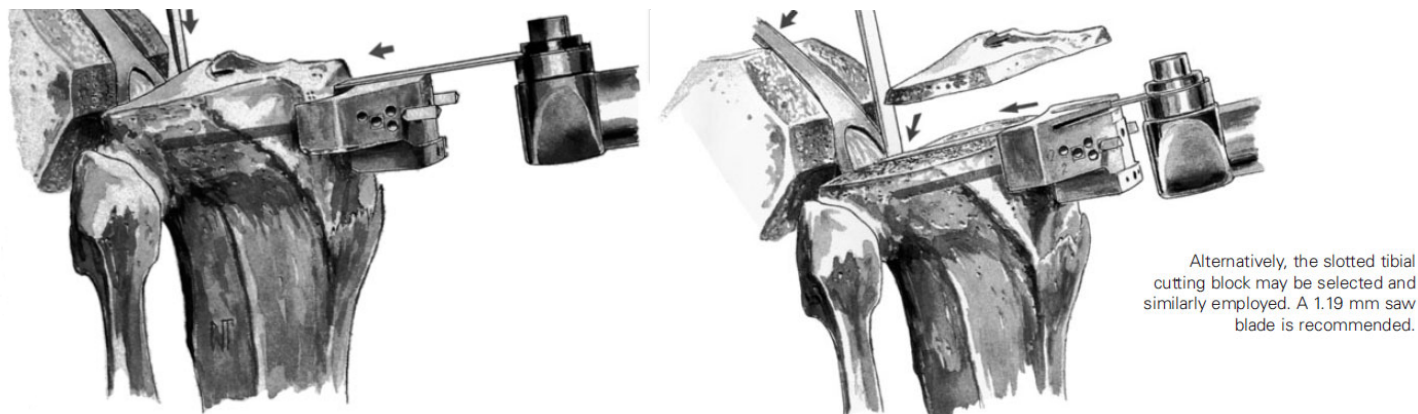
○

The oscillating saw blade is positioned flush to the cutting surface of the block or, where applicable, through the slots. The condyles are resected and the surface checked for accuracy.



- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 25

○



A person of ordinary skill in the art would have been motivated to combine the teachings of the PFC Sigma System with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the PFC Sigma System comes from the same area of art as many of Defendants' identified references—*i.e.*, instruments to perform total knee arthroplasty. Furthermore, the PFC Sigma System teaches that “[t]he instruments may be customized to meet any special requirement of the individual surgeon.” PFC Sigma System at 7. For example, the PFC Sigma System offers both “slotted and surface-cutting blocks.” *Id.* Thus, a POSITA would be motivated, to the extent not already disclosed to include cutting surfaces and/or cutting slots based off surgeon preference.

E. First and Second Guide Limitations

First and second guides for tools, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
745	46	The surgical instrument of claim 1, further comprising a second guide, wherein the first guide is aligned through a first portion of the joint and the second guide is aligned through a second portion of the joint when the patient-specific surface is placed against and aligned with the corresponding cartilage surface.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Asserted Patents

- '745 Patent, 69:11-15; '482 Patent, 69:19-23; '161 Patent, 69:20-24; '129 Patent, 43-65-44:2; '304 Patent, 44:3-7; '026 Patent, 52:59-63; '780 Patent, 6-10
 - Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee.
- '745 Patent, 97:57-61; '482 Patent, 98:1-5; '161 Patent, 98:1-5; '026 Patent, 80:65-81:2; '780 Patent, 81:10-14
 - For example, a standard surgical cut block as described for standard implants, for example in the knee the J&J PFC Sigma system, the Zimmer Nexgen system or the Stryker Duracon system, can be connected or placed on the mold.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught first and second guides. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that the use of guides can increase accuracy and efficiency in surgery, including specifically in knee surgery. Furthermore, the Charted References taught the use of design considerations such as individualized and/or standard/reusable guides with the specific types and number of apertures being selected depending on the type of surgery being performed, manufacturing consideration,

etc. Thus, a person of ordinary skill in the art would have been motivated by the Charted References to include first and second guides in a patient-specific instrument to yield the predictable benefit of a design suited for the particular surgery being performed.

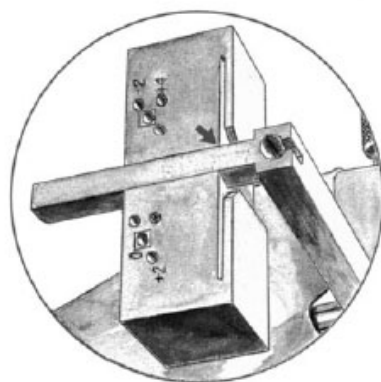
3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. PFC Sigma System (DPY_00009219 to DPY_00009477)

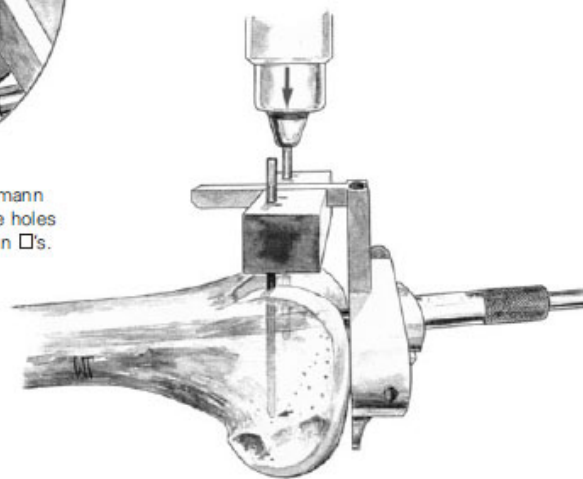
- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 12

○



Either 1/8 inch drill bits or Steinmann pins are introduced through the holes designated zero and enclosed in □'s. They are advanced into the anterior cortex.

Alternatively, the cutting block is available in a slotted version. A 1.19 mm saw blade is recommended.

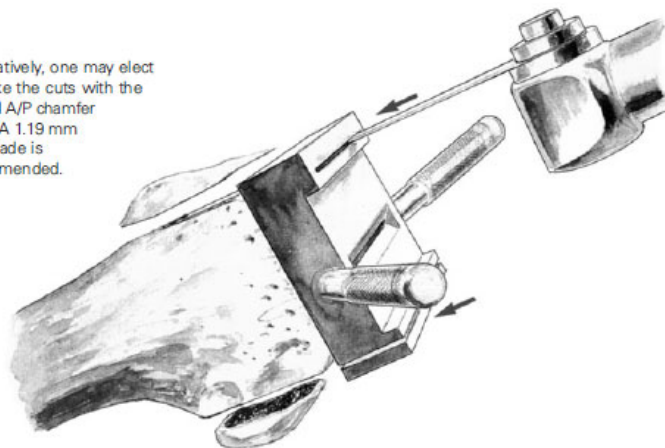


It is easier to drill the lateral first.

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 16

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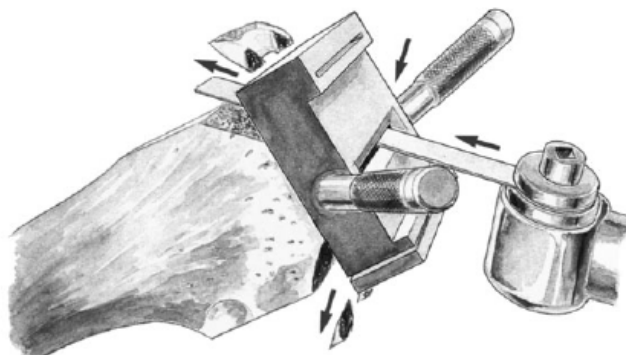
Alternatively, one may elect to make the cuts with the slotted A/P chamfer block. A 1.19 mm saw blade is recommended.



- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 17

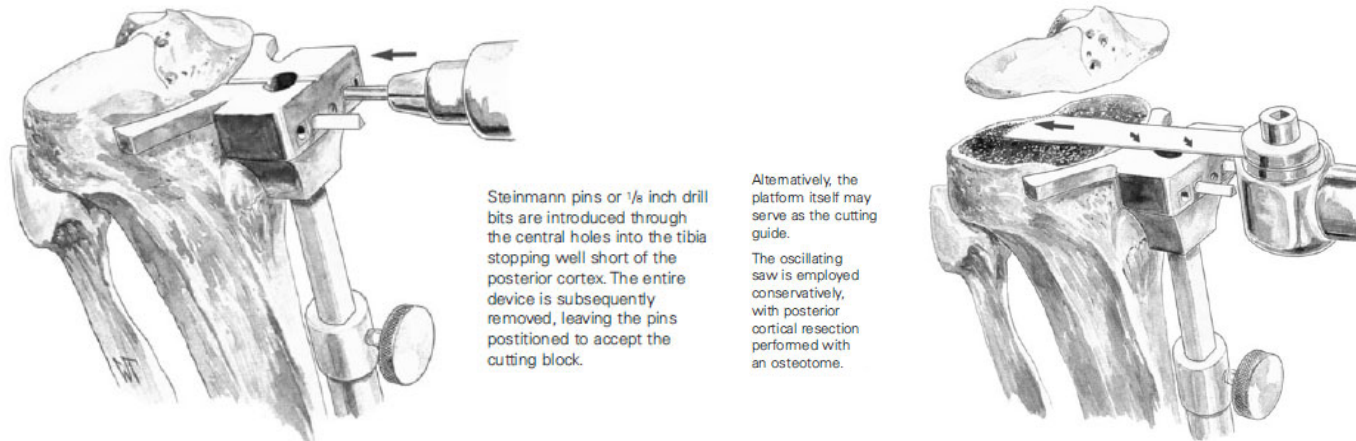
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Alternatively, the chamfers are made with the slotted A/P block.



- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 22

○



A person of ordinary skill in the art would have been motivated to combine the teachings of the PFC Sigma System with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the PFC Sigma System comes from the same area of art as many of Defendants' identified references—*i.e.*, instruments to perform total knee arthroplasty. Thus, it would be obvious to a POSITA to include first and second guides in a patient-specific template.

ii. Radermacher Thesis

- Figure 7-5

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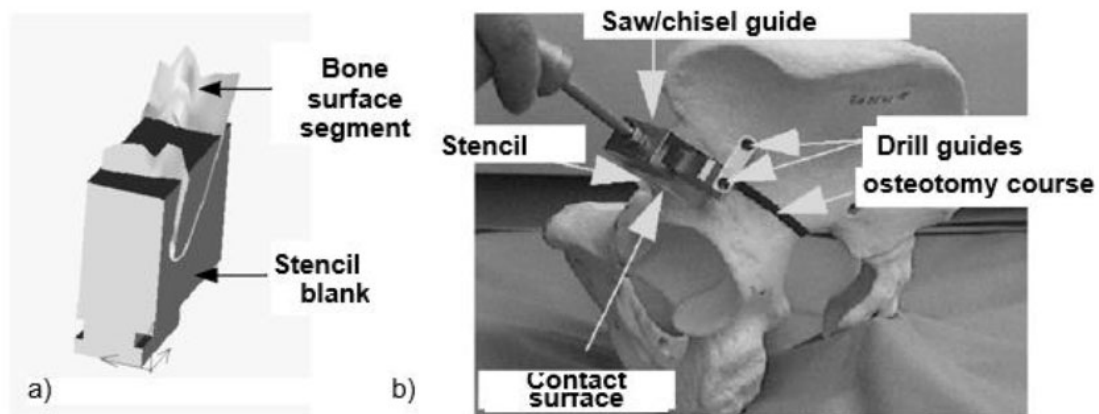
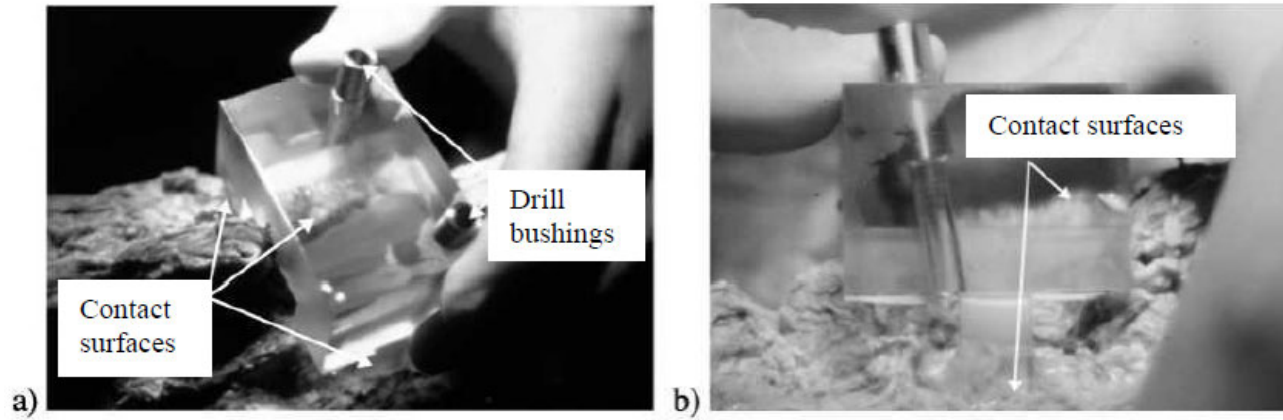


Figure 7-5: Preclinical studies - a) CAD representation of a template blank (for the quick adapter system shown in section 5.3) with the contact surface segment to be milled out; b) Testing on the bone model - quick adapter system with drill guides and individually adapted contact surface.

- Figure 4-34

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- Figure 4-36

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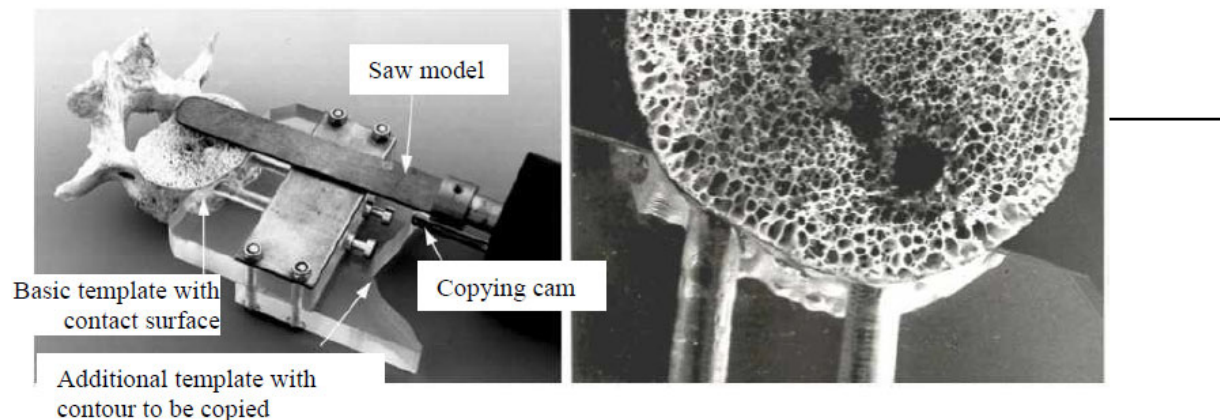


Figure 4-36: Ventral vertebral body osteotomy with depth-of-cut limitation: a) template and vertebral bone after osteotomy has been performed using the model of a TUKE saw with copying cam (the additional parallel guide was dismantled for display reasons). The contour to be copied and copying cam limit the movement of the tip of the saw blade exactly to the dorsal surface contour of the vertebral body; b) detailed image of the osteotomy plane showing the contact between CT-image-based base template and bone

- Pages 55-56

- 4.1 The concept of customized templates

The aim of the development is, on the one hand, to support the planning of surgical corrective procedures on bone structures by computer-aided preprocessing and reconstruction of three-dimensional CT image data, by linking additional information specific to the procedure or implant, and by additional tools for analysis and simulation. On the other hand, the preoperative planning information is to be stored and processed, in such a way, that intraoperative processing of the real bone structure, with conventional processing tools, is possible with corresponding accuracy.

The basic idea of the developed solution approach is to supplement the information of the exact spatial position, relative to the bone, which is missing from the conventional standard templates, based on individual CT image-based bone geometry model data, as well as the individual spatial planning of the surgeon. This is intended to exploit the advantages of conventional processing devices, to increase their accuracy, but also to create implementation aids for orthopedic procedures for which no processing devices are currently available.

Individual templates will be constructed on a patient-specific basis, using 3D reconstructions of preoperative CT image information. In addition to the surgical processing geometries, attachment areas of the template on the natural surface of the bony structure, which are conventionally accessible to the surgeon, are also defined as reference structures.

These segments of the individual bone surface geometry, reconstructed from CT data, are then structurally incorporated preoperatively into a corresponding template element under computer control, in such a way, that a clearly defined positive fit of the template, on the corresponding natural surface of the bone, is ensured and a planned position can thus be retrieved intraoperatively.* In addition, tool guides are integrated or adapted into the template elements, in position and orientation according to the planned processing geometry. . . . The solution concept is thus based on the process concept shown schematically in Figure 4-2, which is to be included in the further development and evaluation of the solution approach.

- Figure 4-1

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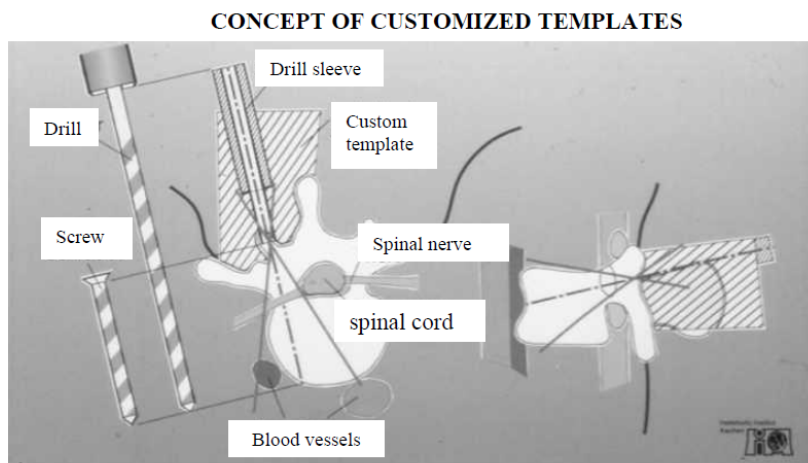


Figure 4-1: Schematic representation of the positioning of tool guides, by means of individually form-fitted reference surfaces or “contact surfaces”, adapted to segments of the natural bone surface.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach patient-specific templates for total knee arthroplasty. *See, e.g.,* Radermacher Thesis at 3 (“Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen.”).

Radermacher Thesis also teaches that the disclosed templating technique can be applied to total knee arthroplasty, the same surgical procedure addressed by many of the references identified in Defendants' Invalidity Contentions, *see, e.g., id.* at Fig. 4-37, and that first and second tool guides can be included in the template. *See, e.g., id.* at Figs. 4-34, 4-36, 4-37 & 7-5. Thus, to the extent not disclosed a POSITA would find it obvious to include first and second guides in a template.

F. "Predetermined Path" Limitations

A guide having a predetermined path for a surgical tool, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
482	1	wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.
482	17	have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.
745	1	the guide having a position and orientation relative to the patient-specific surface to define a predetermined cutting path for the surgical tool that is aligned through a portion of tissue associated with the diseased or damaged joint when the patient specific surface is placed against and aligned with the corresponding cartilage surface; and

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

- i. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018⁵

⁵ In the quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

- Pages 12-13

- For the last four decades (and still today), the majority of total knee arthroplasties have been performed using a rod-based system to properly align cutting guides. Rod-based systems use a combination of intramedullary and extramedullary rods to facilitate the placement of cutting guides. . . . The cutting guide includes one or more cutting paths that guide tools, e.g., a saw, that the surgeon will use to resect the femur. To ensure proper alignment, the femoral cutting guide must be placed and adjusted so the resection of the distal femur is perpendicular to the mechanical axis. Because the intramedullary rod approximates the anatomical axis, the cutting path in the femoral cutting guide must be oriented according to the preoperatively determined offset between the femoral anatomical axis and femoral mechanical axis.

ii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

- Paragraph 28

- The inserted intramedullary rod approximates the patient's femoral anatomical axis. A distal femoral cutting guide is then attached to the end of the intramedullary rod. This cutting guide is either selected or adjusted based on the preoperatively determined angle³ between the femoral anatomical and mechanical axes. The cutting guide is associated with the femoral anatomical axis because of the intramedullary rod, and the preoperatively determined angle is used to identify a cutting path perpendicular to the femoral mechanical axis. Both types of cutting guides rely on the preoperatively determined angle to ensure that the distal femoral cut is made perpendicular to the femoral mechanical axis. In other words, the intramedullary rod approximates the patient's femoral anatomical axis, but the distal femur must be cut perpendicular to the femoral mechanical axis. Consequently, the surgeon must use the preoperatively determined relationship (angle) between the femoral anatomical and mechanical axes to select or adjust the distal femoral cutting guide such that the distal femoral cut is perpendicular to the femoral mechanical axis.

- Paragraph 60

- *Berez* describes patient-specific cutting guides for use in joint arthroplasty procedures. Ex.B at Title, Abstract; *see also id.* ¶¶ [0265]-[033 l]. The cutting guides have a surface that will match a portion of an articular or a bone surface. *Id.* ¶ [0266]. The guides also have apertures, slots, and/or holes to accommodate surgical tools such as saws and drills. *Id.* *Berez* explains that "[t]ypically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general [cutting

guide] orientation for subsequent placement of an articular repair system [(implant)] or for facilitating placement of the articular repair system [(implant)]." *Id.* ¶ [0267].

- Paragraph 68
 - *Radermacher* describes reconstructing tomographic images into a three-dimensional image of the osseous structure. *Id.* at 12. And with a computer system, a "three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure" is generated. *Id.* *Radermacher* explains that this negative mold of the bone surface can be used to construct the contact surface of the cutting guide. *Id.*
- Paragraph 69
 - In addition, cutting paths may be included "in/on the basic body" of the cutting guide. *Id.* at 13. The cutting paths are oriented or constructed "relative to the [three-dimensional] reconstruction of the osseous structure" to "effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by [preoperative] planning." *Id.* That is, the treatment steps defined in preoperative planning "can be exactly transferred since, relative to the osseous structure, the [cutting paths] can be brought exactly into the positions defined during [preoperative] planning." *Id.* at 14-15. "To this purpose, the [cutting guide] with the faces of the negative mold is set under mating engagement onto the then exposed bone surface . . . without any further intraoperative devices . . . and without intraoperative measuring and positioning work." *Id.* at 15. *Radermacher* notes that "nails, screws and the like" may be used to fix the cutting guide to the bone. *Id.* at 25.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught a guide having a predetermined position, including in relation to a patient-specific surface. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that guides having a position and orientation relative to the patient-specific surface to provide a predetermined path for a tool can increase the accuracy of the work done to the bone. Furthermore, many of the Charted References taught guides having a position and orientation relative to the patient-specific surface to provide a predetermined path for a tool in instruments for total joint arthroplasty, including total knee arthroplasty. Thus, a person of ordinary skill in the art would have been motivated by Charted References to includes one or more guides having a position and orientation relative to the patient-specific surface to provide a predetermined path for a tool on an instrument for total knee arthroplasty.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Vomlehn

- [0038]
 - In an optional embodiment, user 3 also may use a pointing device of user interface 17 to select a position and orientation (pose) which in a surgical instrument 40 is positioned in order to correctly insert the screw or pin. Design device 25 or graphics engine 21 may have a computer model of surgical instrument 40 pre-stored, and superimpose this model upon the images provided on monitor 23.
- [0040]
 - The final pose of surgical instrument may be used to construct a guide hole 31. Guide hole 31 allows is a shaft 41 of medical equipment, such as a surgical drill 40, to fit through snugly with little clearance, intended to restrain motion of the drill 40 along in all directions except along an axis of guide hole 31.

- Figure 2

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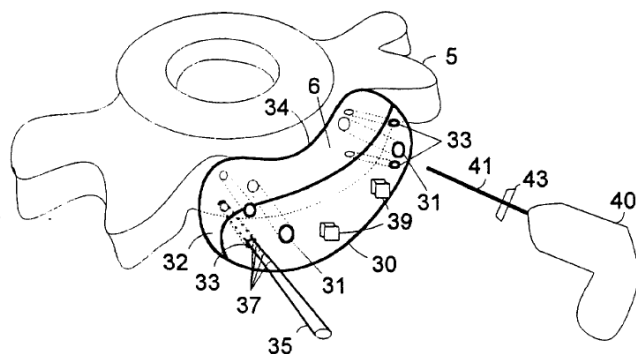


Fig. 2

A person of ordinary skill in the art would have been motivated to combine the teachings of Vomlehn with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the teachings in Vomlehn could be applied to a wide variety of orthopedic procedures, including total knee arthroplasty. *See, e.g.*, [0001] ("The present invention relates to computer-aided construction of a reference structure to be attached to a subject and act as a guide in medical procedures."); [0002] ("In various medical procedures, it is necessary to attach a piece of medical equipment into a solid structure of the subject."). Furthermore, Vomlehn teaches that having a patient-specific template with a guide can increase the accuracy of medical procedures and eliminate estimation by surgeons or the use of intraoperative imaging. *See, e.g.*, [0006] ("Typically, these pins or screws have been inserted by a surgeon who visually, or by 'feel', finds the approximate location where the screw or pin should be entered, and drills a hole at that location. The screw or pin is inserted into the hole."); [0007] ("Sometimes, during surgery, two dimensional (2D) snapshots such as x-rays or magnetic resonance (MR) images may be obtained"); [0013]-[0014] ("Currently there is a need for a device which may be attached to a subject and act as a reference structure to guide instruments during medical procedures. The present invention constructs a reference structure intended to be attached to a solid anchor site of a subject."). Thus, to the extent not disclosed, a POSITA would be motivated to include a guide with a predetermined path for a surgical tool in a patient-specific template.

ii. Radermacher CAOS

- Page 28

- An alternative technique for computerized tomographic image based preoperative three-dimensional planning and precise surgery on bone structures using individual templates has been developed. For the preoperative customization of these mechanical tool guides, a desktop computer controlled milling device is used as a three-dimensional printer to mold the shape of small reference areas of the bone surface automatically into the body of the template. Thus, the planned position and orientation of the tool guide in spatial relation to bone is stored in a structural way and can be reproduced intraoperatively by adjusting the position of the customized contact faces of the template until the location of exact fit to the bone is found. No additional computerized equipment or time is needed during surgery. The feasibility of this approach has been shown in spine, hip, and knee surgery, and it has been applied clinically for pelvic repositioning osteotomies in acetabular dysplasia therapy.

- Page 29

- In orthopaedic surgery standard template systems are familiar technical means to guide drills and saws in total knee replacement. However, the design of these tool guides is based on averaged anatomic geometries. The positioning of the template on the bone bears no precise relationship to the position defined by individual preoperative planning.

Essentially, the missing information is the precise spatial correspondence between the individual bone structure in situ and the intended position of the tool guides. The authors investigated a means of adding this missing information to the classic templates by providing shape based physical matching between the reference surface of the individual bone and the reference surface of the computer based model. This information is incorporated into an individual template.¹²⁻¹⁶

Individual templates are customized on the basis of three-dimensional reconstructions of the bone structures extracted from computerized tomographic (CT) image data in accordance with individual preoperative surgical planning. For preoperative customization, a low cost desktop milling machine is used as a three-dimensional printer to mold the shape of a small reference area on the individual bone automatically into the template. By this means the planned position and orientation of the tool guide in spatial relation to the bone is stored in a structural way and can be reproduced in situ adjusting the position of the contact faces of the template until they fit exactly on the bone (Fig 1). Neither iterative time consuming work under radiographic control or registration procedures, nor any additional computerized equipment is needed intraoperatively. Mechanical guides for drills, saws, chisels, or milling tools are adaptable or integrated into these individual templates in predefined positions for different types of interventions. Moreover, individual templates also can be used for fixation of a reference base for standard tool guides or other devices in a defined position on bone.

- Page 30
 - Among the applications of this technique are pedicle screw placement (especially in scoliosis therapy; Fig 2); repositioning osteotomies in spine surgery; puncture of a cystic cavity in the femoral head; intertrochanteric repositioning osteotomy; initial reference osteotomies for total knee replacement (especially in the case of pathologic deformations); . . .
- Pages 30-31
 - The authors selected this application for their initial investigations of the principle of individual templates^{12,13} (Fig 1). Human anatomic specimens of lumbar spines were scanned with CT (slices 2-mm thick and 2-mm apart). The image data were transferred to the personal computer based DISOS planning workstation (Gemetec mbH, Aachen, Germany). Based on three-dimensional reconstructions automatically provided by the system, the surgeon selects an appropriate screw and defines its optimal placement (Fig 1B). The position and orientation of the related drill guide then is specified and can be incorporated into the individual template. To provide shape based intraoperative matching, small reference contact faces to the vertebral bone have to be specified on the display in the vicinity of the transverse process, the arch, or the spinous process. To this end, the surgeon interactively selects and positions an appropriate template within the three-dimensional view of the vertebral bone structure (Fig 1C). . . . Intraoperatively, the defined position of the bore is reproduced by placing the self locating template where it fits exactly on the bone.

- Figure 1

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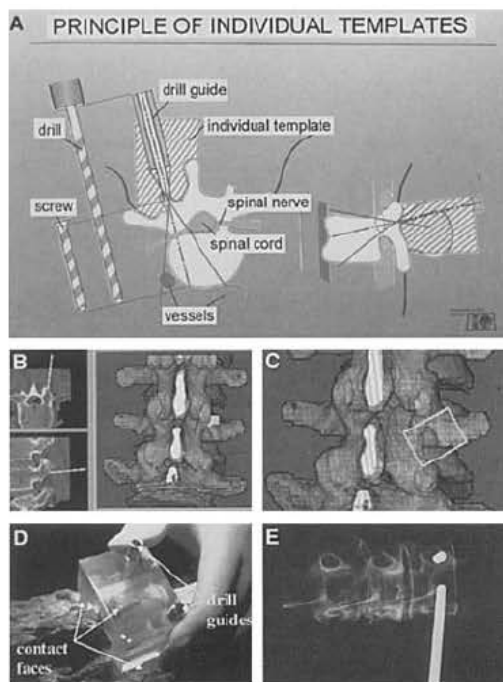


Fig 1. Pedicle screw placement: (A) the principle of individual templates based on preoperative CT imaging and computer based planning; (B) computer assisted planning of a pedicle screw placement with the DISOS planning system; (C) interactive specification of the reference contact face; (D) formclosed intraoperative fitting of the template; and (E) radiographic control of the placement of 5-mm rods in the pedicles without any perforation in situ.

- Page 31

- In total knee arthroplasty accurate placement of implant components with respect to the individual mechanical axis of the leg is essential. Conventionally, modular mechanical devices corresponding to the intrinsic shape of the implant components are used to guide the osteotomies and bores for the preparation of the implant's seat. By mounting these conventional tool guide systems on an individual template as a basic customized reference, it is possible to reproduce the preoperatively planned position exactly even in the case of severely deformed bone.

- Figures 2A-B

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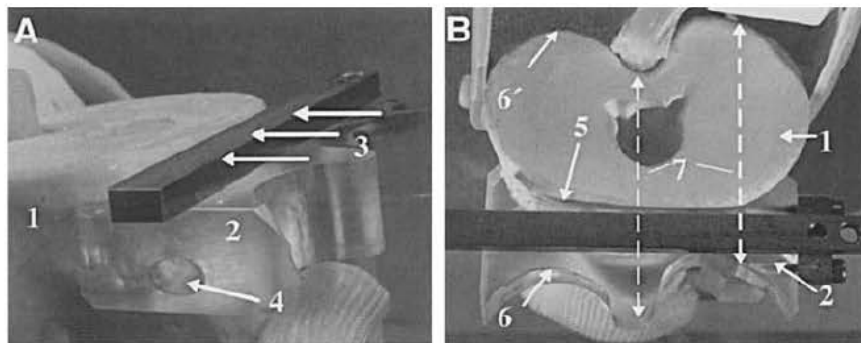


Fig 2A–B. Total knee arthroplasty: (A) laboratory investigation on a plastic bone model (1): individual template guiding the reference osteotomy (3) in tibial bone, optional fixation with a bone pin (4); (B) customized reference contact face (5) and copying profile (6) limiting cutting depth (7) to the dorsal contour (6) of tibial bone.

- Pages 31-32

- Figure 2 shows a feasibility study with a CT image based individual template for the reference tibial cut for total knee replacement on a plastic bone model.¹⁵ The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). In addition, topograms could be used to identify the bone axis. A conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone. The template has been customized in the areas of the reference surface and the individual copying profile

corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher CAOS and many of the references identified in Defendant's Invalidity Contentions, including the Charted References, come from the same field of invention and disclose patient-specific guides for total knee arthroplasty. Furthermore, Radermacher CAOS teaches that its approach can increase accuracy and reduce costs. *See, e.g.*, Radermacher CAOS at 31-32 ("The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes."); Page 29 ("The goal of the work described here was to develop a relatively simple, low cost solution that facilitates exact, safe, and fast implementation of planned surgery on bone structures, eliminates the need for continual radiographic monitoring, and avoids overburdening surgery with complex equipment and time consuming procedures."); Page 36 ("The individual template approach represents a relatively simple, low cost, and easy to use solution that facilitates precise preoperative planning and appropriate intraoperative implementation. The conventional intraoperative procedure is preserved and no additional intraoperative registration steps, computerized equipment, space, or personnel are needed."). Thus, a POSITA would be motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References.

iii. Radermacher Thesis

- Pages 55-56

- 4.1 The concept of customized templates

The aim of the development is, on the one hand, to support the planning of surgical corrective procedures on bone structures by computer-aided preprocessing and reconstruction of three-dimensional CT image data, by linking additional information specific to the procedure or implant, and by additional tools for analysis and simulation. On the other hand, the preoperative planning information is to be stored and processed, in such a way, that intraoperative processing of the real bone structure, with conventional processing tools, is possible with corresponding accuracy.

The basic idea of the developed solution approach is to supplement the information of the exact spatial position, relative to the bone, which is missing from the conventional standard templates, based on individual CT image-based bone geometry model data, as well as the individual spatial planning of the surgeon. This is intended to exploit the advantages of conventional processing devices, to increase their accuracy, but also to create implementation aids for orthopedic procedures for which no processing devices are currently available.

Individual templates will be constructed on a patient-specific basis, using 3D reconstructions of preoperative CT image information. In addition to the surgical processing geometries, attachment areas of the template on the natural surface of the bony structure, which are conventionally accessible to the surgeon, are also defined as reference structures.

These segments of the individual bone surface geometry, reconstructed from CT data, are then structurally incorporated preoperatively into a corresponding template element under computer control, in such a way, that a clearly defined positive fit of the template, on the corresponding natural surface of the bone, is ensured and a planned position can thus be retrieved intraoperatively.* In addition, tool guides are integrated or adapted into the template elements, in position and orientation according to the planned processing geometry. . . . The solution concept is thus based on the process concept shown schematically in Figure 4-2, which is to be included in the further development and evaluation of the solution approach.

- Figure 4-1

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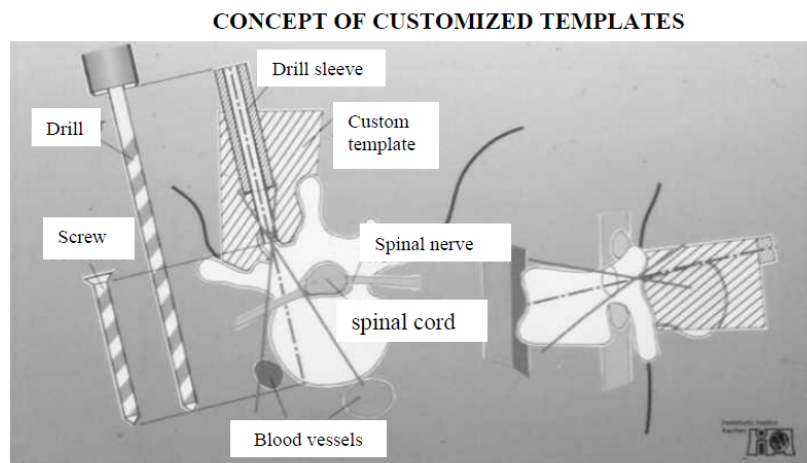


Figure 4-1: Schematic representation of the positioning of tool guides, by means of individually form-fitted reference surfaces or "contact surfaces", adapted to segments of the natural bone surface.

- Page 105

- 4.5.1 Transpedicular drilling

In initial studies, the application of transpedicular drilling in vertebral bones, described at the beginning of Section 2.1.3, was investigated on anatomical specimens. In order to ensure stable fixation of the screw in the cortical bone, the choice of diameter and length, as well as the best positioning of the screw in the pedicle and vertebral body is essential. Perforations can lead to weakening of the bone structure, spinal cord injury, or lesions of nerves and blood vessels. The problem has already been clarified in Section 2.1.3 and in Figure 4-1.

A fresh anatomical specimen of human lumbar vertebrae was scanned by computed tomography (slice spacing/thickness: 2 mm/2 mm, gantry angle: 0°, tube current-recording time product: 200 mAs, tube voltage: 120 kV, reconstruction filter:

standard). For the purpose of simulating real surgical access and conditions of the bone/template contact area, the muscle and soft tissue was largely preserved. The preparation was then preserved in formalin solution. The CT data were transferred to the image processing computer and reconstructed in three dimensions. The structure of the bone was segmented with a global threshold of 170 HU. After selecting the diameter and length of the screw and drill, the position of the hole was defined. To this end, an entry point is first selected in the 3D view of the vertebral body, and then the position and orientation of the screw is checked and adjusted using the 3D view and gray-scale sectional images perpendicular to the screw axis (cf. Figure 4-19). The attachment areas of the customized templates were selected in this case in the region of the transverse processes and the spinous process.* The evaluation of the surface topography, with regard to the possibility of a clear position determination by contact surfaces in the selected area, was carried out purely subjectively on the basis of the 3D views.

During the preliminary investigations, the inner and outer contours of the bone structure were extracted using the described procedures and transferred to a commercially available CAD system (ICEM DDN/Control Data Inc.) together with the planning geometries. Figure 4-33a) shows the positional relationship of drill holes, anatomical structures and defined reference areas of the bone surface. This positional relationship is structurally stored in a customized template (Figure 4-33b). The connection structure of the template was built from simple control elements and adapted to the conditions of the surgical access. This resulted in defined reference and clamping surfaces for milling operations.

Narrow bars connect small reference surfaces in the area of the transverse processes here with a more solid connecting structure for individual alignment of the drill sleeves and the connecting bar with contact surface in the area of the spinous process.

The interpolated surface segments were checked for undercut on the CAD system and modified, if necessary. The NC toolpaths were generated on the CAD system and transferred to the NC machine. The template element was customized in the areas of the contact surfaces using 3-axis NC milling. In addition, the drill bushings were individually incorporated, in terms of position and orientation, in accordance with the planning. . . .

The template was first steam sterilized. Soft tissue preparation and execution of the drill holes were performed by an orthopedic surgeon, with many years of clinical experience in spine surgery, using standard surgical instruments. The bone surface was exposed in the appropriately planned areas in a conventional manner. The reference position of the template could be found again reliably.

The 5-mm holes were drilled using electric drills, with the template held by hand on the bone. The usual inspection of the drill channel by means of hook probe did not reveal any perforations. In addition, radiographic control images were taken, which confirmed the correct positioning of the drill holes according to the planning (Figure 4-34).

- Figure 4-33

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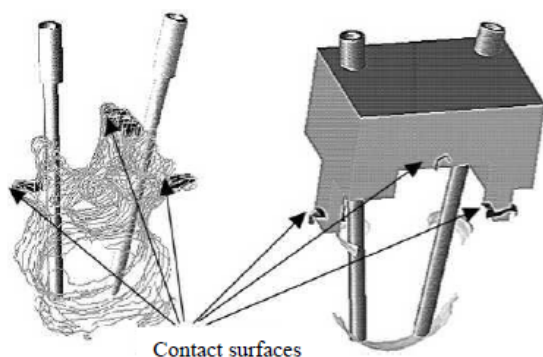


Figure 4-33: Saving of the planning in individual templates: a) representation of the positional relationship between bone structure drill holes and contact surfaces in the CAD system; b) saving of the positional relationship in a template element with integrated individually aligned drill bushings (the critical structures, i.e., pedicle and ventral surface of the vertebral body, are indicated).

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach patient-specific templates for total knee arthroplasty. *See, e.g.,* Radermacher Thesis at 3 ("Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen."). Radermacher Thesis also teaches that the disclosed templating technique can be applied to total knee arthroplasty, the same surgical

procedure addressed by many of the references identified in Defendants' Invalidity Contentions. *See, e.g., id.* at Fig. 4-37. Thus, to the extent not disclosed a POSITA would find it obvious to include a guide having a position and orientation relative to the patient-specific surface to provide a predetermined path.

G. Cartilage Limitations

Cartilage information being part of a patient-specific surface, including as recited in the following Asserted Claims, was well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
026	52	at least one surface for engaging a first cartilage surface of a joint,
026	52	the at least one surface being substantially a negative of portions of the first cartilage surface;
129	1	the patient-specific surface including cartilage information derived from image data of the diseased or damaged knee joint of the patient; and
304	4	The surgical instrument of claim 1, wherein the internal surface substantially conforms to the shape of a surface of the joint of the patient, wherein the surface of the joint includes a cartilage surface of the joint and a subchondral bone surface of the joint.
482	1	the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint,
745	1	at least a portion of the patient-specific surface having a shape that is substantially a negative of a corresponding cartilage surface of the diseased or damaged joint; and

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art
 - i. Asserted Patents

- '745 Patent, 31:57-32:3; '482 Patent, 32:3-15; '161 Patent, 32:3-16; '129 Patent, 13:51-64; '304 Patent, 13:54-67; '026 Patent, 24:24-37; '780 Patent, 24:37-50
 - As will be appreciated by those of skill in the art, imaging techniques suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss include the use of x-rays, magnetic resonance imaging (MRI), computed tomography scanning (CT, also known as computerized axial tomography or CAT), optical coherence tomography, ultrasound imaging techniques, and optical imaging techniques. (See, also, International Patent Publication WO 02/22014 to Alexander, et al., published Mar. 21, 2002; U.S. Pat. No. 6,373,250 to Tsoref et al., issued Apr. 16, 2002; and Vandeberg et al. (2002) Radiology 222:430-436). Contrast or other enhancing agents can be employed using any route of administration, e.g. intravenous, intra-articular, etc.
- '745 Patent, 2:66-3:11; '482 Patent, 3:8-21; '161 Patent, 3:7-19; '129 Patent, 2:35-47; '304 Patent, 2:35-47; '026 Patent, 2:51-63; '780 Patent, 2:51-63
 - Usually, severe damage or loss of cartilage is treated by replacement of the joint with a prosthetic material, for example, silicone, e.g. for cosmetic repairs, or metal alloys. See, e.g., U.S. Pat. No. 6,383,228 to Schmotzer, issued May 7, 2002; U.S. Pat. No. 6,203,576 to Afriat et al., issued Mar. 20, 2001; U.S. Pat. No. 6,126,690 to Ateshian, et al., issued Oct. 3, 2000. Implantation of these prosthetic devices is usually associated with loss of underlying tissue and bone without recovery of the full function allowed by the original cartilage and, with some devices, serious long-term complications associated with the loss of significant amount of tissue and bone can include infection, osteolysis and also loosening of the implant.
- '745 Patent, 43:4-15; '482 Patent, 43:14-24; '161 Patent, 43:14-25; '129 Patent, 17:59-18:3; '304 Patent, 17:65-18:6; '026 Patent, 35:37-47; '780 Patent, 35:50-61
 - Devices suitable for obtaining intraoperative measurements of cartilage or bone or other articular structures, and to generate a topographical map of the surface include but are not limited to, Placido disks, optical measurements tools and device, optical imaging tools and devices, and laser interferometers, and/or deformable materials or devices. (See, for example, U.S. Pat. No. 6,382,028 to Wooh et al., issued May 7, 2002; U.S. Pat. No. 6,057,927 to Levesque et al., issued May 2, 2000; U.S. Pat. No. 5,523,843 to Yamane et al. issued Jun. 4, 1996; U.S. Pat. No. 5,847,804 to Sarver et al. issued Dec. 8, 1998; and U.S. Pat. No. 5,684,562 to Fujieda, issued Nov. 4, 1997).

ii. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018⁶

- Pages 5-6

- Damage to the knee joint can occur by acute trauma or through chronic degeneration. Osteoarthritis is a common example of chronic cartilage degeneration. And because cartilage has a limited ability to repair itself, cartilage damage can be quite detrimental. Under even normal use, articular cartilage can soften and wear away, reducing lubrication, disrupting normal load transfer, and making articulation more difficult. It is relatively common for articular cartilage to completely wear away (at least in some areas), exposing the underlying subchondral bone. This typically occurs on both femoral and tibial aspects of the knee joint and leads to bone-on-bone articulation between the distal end of the femur and the proximal end of the tibia. This can be quite painful and leads to joint inflammation and reduced function.

Cartilage degeneration is often categorized into five grades based on degree or severity of damage. The first, "Grade 0," is assigned to healthy articular cartilage. "Grade 1" is assigned to articular cartilage that has started to swell and soften. This may be in response to normal wear or a localized injury. "Grade 2" is assigned to cartilage with a "partial-thickness (less than 50%) defect with fissures, ulceration, and fibrillation on the surface." "Grade 3" is assigned to cartilage with a "partial-thickness (greater than 50%) defect with fissures, ulceration, and fibrillation on the surface." *id.* And "Grade 4," the most severe, is assigned to cartilage with a "full thickness (100%) defect with exposed subchondral bone (bone-on-bone)." With every increase in the degree of cartilage damage, available means of treatment and repair become more drastic. Once "Grade 4" damage is realized, the only solution is usually a total knee replacement procedure, or "total knee arthroplasty."

iii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

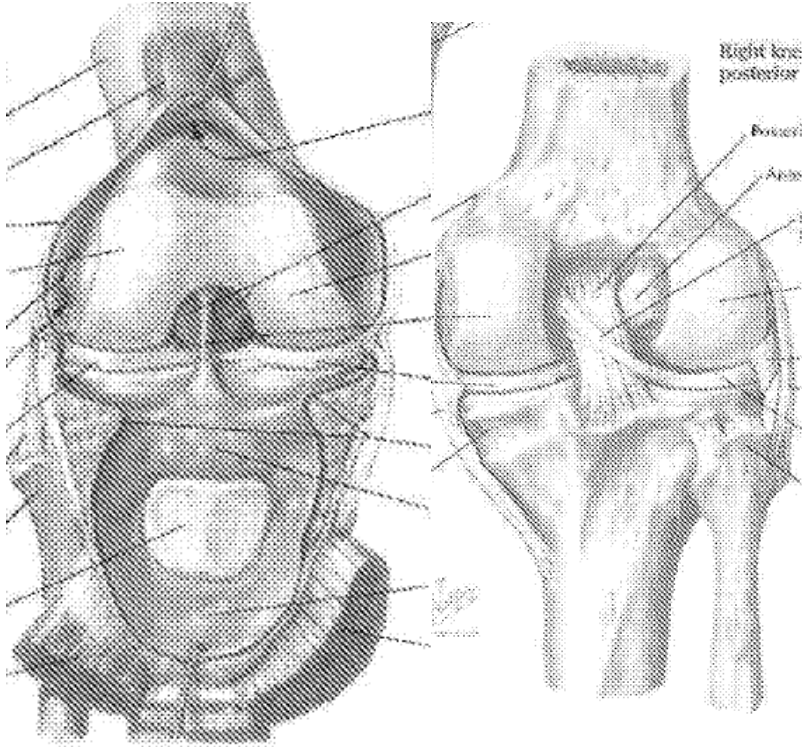
- Paragraph 12

- The ends of the femur and tibia and the underside of the patella are covered by articular cartilage, which reduces friction and distributes loads during articulation of the knee. Articular cartilage is avascular, meaning it lacks blood vessels. Articular cartilage is instead nourished by synovial fluid secreted by a relatively thin membrane surrounding the cartilage known as the synovium. Because articular cartilage lacks blood vessels, it does not possess the regenerative capacity of other types of tissues.

⁶ In the quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

- Paragraph 14, Pages 5-6

- The figures below depict the anatomy of the knee joint, including the components I have described above.



- Paragraph 15

- Osteoarthritis is an age-related condition affecting many joints, including the knee joint. Because articular cartilage has a very limited ability to repair itself, it degenerates (e.g., softens and wears away) over time through even relatively regular activity. This in turn adversely affects the function of the joint, causing pain and stiffness and limiting movement. Osteoarthritis of the knee often occurs in people over fifty years of age, though it may occur in younger people as well. As

the articular cartilage degenerates, the underlying subchondral bone will eventually become exposed, and the distal femur and proximal tibia bones will grind against one another.

- Paragraph 16
 - Cartilage degeneration is often categorized into five grades:
 - a. Grade 0 - normal cartilage;
 - b. Grade 1 - cartilage with softening and swelling;
 - c. Grade 2 --- cartilage with a partial-thickness (less than 50%) defect with fissures, ulceration, and fibrillation on the surface;
 - d. Grade 3 - cartilage with a partial-thickness (greater than 50%) defect with fissures, ulceration, and fibrillation on the surface; and
 - e. Grade 4 - cartilage with a full thickness (100%) defect with exposed subchondral bone (bone-on-bone).

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught at least one surface for engaging/being a negative of/including image data of cartilage. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, many of the Charted References come from the same field of invention—tools for joint arthroplasty, more specifically tools for total knee arthroplasty. Additionally, the charted references taught having at least one surface for engaging/being a negative of/including image data of cartilage in a patient-specific template can increase the accuracy of the work done to the bone. Thus, it would be obvious to a POSITA to combine any of the charted references.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Alexander

- Page 2

- Magnetic resonance imaging (MRI) is an accurate non-invasive imaging technique for visualization of articular cartilage in osteoarthritis, particularly in knees.

- Pages 11-12

- In Figure 1, the first step 10 represents obtaining an image of the cartilage itself. This is typically achieved using MRI techniques to take an image of the entire knee and then, optionally, manipulating (e.g., "subtracting out" or "extracting") the noncartilage images as shown in step 12. Non-cartilage images typically come from bone and fluid. Preferably, the MRI is taken using external markers to provide reference points to the MRI image (step 11).

- Page 12

- With a full 3D image captured, various "maps" or displays of the cartilage can be constructed to give a cartilage degeneration pattern. This is represented by step 16. One such display can, for example, be a color-coding of a displayed image to reflect the thickness for the cartilage. This will allow easy visual identification of actual or potential defects in the cartilage.

- Page 14

- *Imaging Articular Cartilage*

In general, the joint of a patient is that place of union, more or less movable, between two or more bones. A joint comprises cartilage and other elements such as the accompanying bones on either side of the joint, fluid, and other anatomical elements. Joints are classified into three general morphological types: fibrous, cartilaginous, and synovial. This invention is particularly useful for assessing synovial joints, particularly the knee.

- Pages 14-15

- MRI, with its superior soft tissue contrast, is the best technique available for assessing tissue and its defects, for example articular cartilage and cartilage lesions, to obtain a cartilage degeneration can provide morphologic information about the area of damage. Specifically, changes such as fissuring, partial or full thickness cartilage loss, and signal changes within residual cartilage can be detected.

The reason MR imaging techniques are particularly suitable for cartilage is because they can provide accurate assessment of cartilage thickness, demonstrate internal cartilage signal changes, evaluate the subchondral bone for signal abnormalities, and demonstrate morphologic changes of the cartilage surface.

MRI provides several important advantages over other techniques in this invention. One advantage is good contrast between cartilage, bone, joint fluid, ligaments, and muscle in order to facilitate the delineation and segmentation of the data sets. Another is the coverage of the entire region of interest in a single scan within acceptable acquisition times.

- Page 40

- Since the algorithm for 3D surface registration of the femoral condyles also computes the surface normals for the medial and lateral femoral condyles on a pixel-by-pixel basis, it can form the basis for developing maps of cartilage thickness. Fig. 11 shows an example of a 2D map of cartilage thickness derived from the surface normals of the lateral femoral condyle. Figure 11A shows a proton density fast spin-echo MR image that demonstrates a focal cartilage defect in the posterior lateral femoral condyle (black arrows). White arrows indicate endpoints of thickness map. Figure 11 B is a 2D cartilage thickness map that demonstrates abrupt decrease in cartilage thickness in the area of the defect (arrows). The Δ thickness between neighboring pixels can be used to define the borders of the cartilage defect. Note diffuse cartilage thinning in area enclosed by the astericks (*).

- Figures 11A, 11B

○

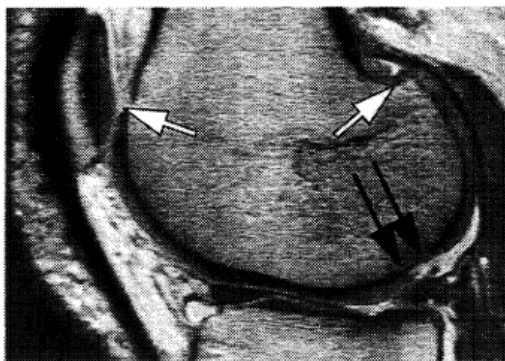


FIG. 11A

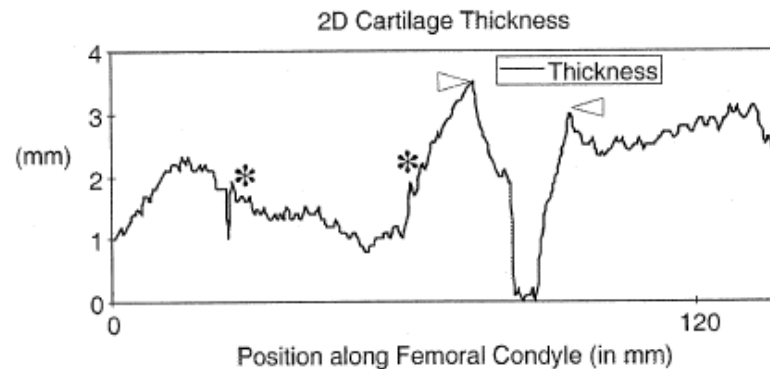


FIG. 11B

- Page 31

- Turning now to Figures 22A and 22B, one can see a 2D MRI (3D SPGR) and 3D cartilage thickness map. In A, the 2D MRI demonstrates a full thickness cartilage defect in the posterior lateral femoral condyle (arrows). Figure 22B shows a 3D cartilage thickness map generated using a 3D Euclidian distance transformation. The thickness of the articular cartilage is color encoded and displayed on a pixel-by-pixel basis along the 3D surface of the articular cartilage. The cartilage defect is black reflecting a thickness of zero (arrows) (M: medial, L: lateral, S: superior, I: inferior).

- Figures 22A, 22B

○

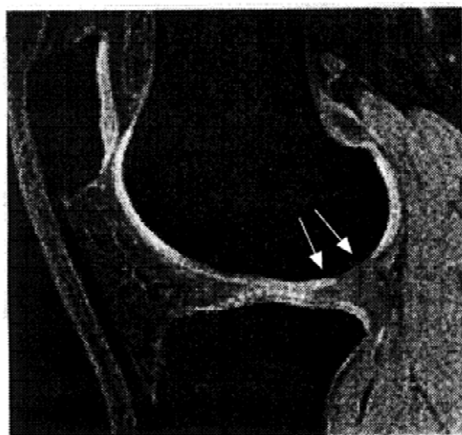


FIG. 22A

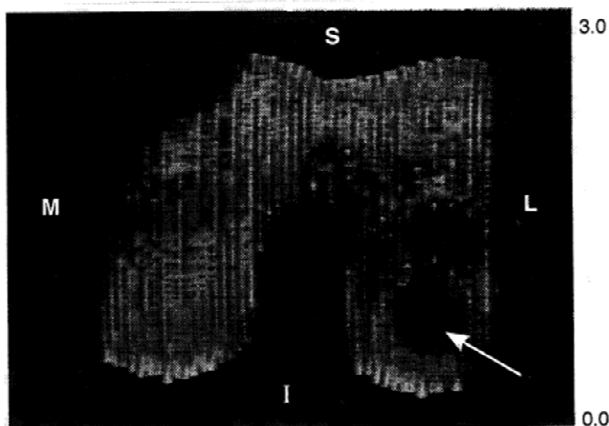


FIG. 22B

- Page 61

- An example of this type of visualization is given in Figure 18. The Figure shows what can be referred to as functional joint imaging. Figure 18A is a photograph demonstrating the position of the external markers positioned around the knee joint. The markers are filled with dilute Gd-solution. B is Sagittal 3D SPGR image through the medial femorotibial compartment. Two of the external markers are seen anteriorly as rounded structures with high signal intensity. C is 3D reconstruction of femoral and tibial bones (light grey), external 20 markers (dark grey), femoral cartilage (red), and tibial cartilage (blue) based on the original SPGR MR images.

- Figure 18C

○



A person of ordinary skill in the art would have been motivated to combine the teachings of Alexander with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Alexander teaches that "Magnetic resonance imaging (MRI) is an accurate non-invasive imaging technique for visualization of articular cartilage in osteoarthritis, particularly in knees" and that the imaging techniques taught in the Alexander are "particularly useful for assessing synovial joints, particularly the knee." Alexander at 2, 14. Many of the Defendants' identified references disclose tools for total knee arthroplasty, and specifically patient-specific tools for total knee arthroplasty with patient-specific surfaces constructed from image data that correspond to areas of the knee where cartilage can be present. Thus, it would be obvious to a POSITA to apply the imaging techniques taught in Alexander to construct a patient-specific surface and include the cartilage information from the imaging in the patient-specific surface. Choosing a cartilage surface in lieu of or in addition to a subchondral surface would also be a design choice as those are a finite number of choices for engagement. To the extent not already disclosed, any resulting modification would merely require combining one known element with another known element to obtain a predictable result of obtaining a device tailored to a patient's cartilage surface and represent a choice from a finite number of identified, predictable solutions with a reasonable expectation of success.

ii. OSTEOARTHRITIS HANDBOOK

- Pages 36-37

- There are many ways in which osteoarthritis begins. Abnormal stress on the cartilage is a major suspect. Scientists are investigating how these disease-initiating stresses differ from the constant, everyday compression, oscillation, twisting, and turning to which cartilage is subjected. Damage to other structures of the joint, such as the ligaments or tendons, may result in abnormal loading of the cartilage and lead to osteoarthritis. . . .

The chondrocytes attempt an unsuccessful repair. There may be bone spur formation or bony overgrowth, both of which aggravate the condition, further impairing motion. Once initiated, the disease process is aggravated because articular cartilage cannot easily repair itself.

This trauma to the cartilage causes a disorganization of the collagen network and promotes water retention. These changes may initiate the disease process. The smooth cartilage surface may become pitted and frayed. Eventually the cartilage may lose some of its ability to hold fluid, thereby becoming less able to withstand loading. This irregular joint surface may begin to interfere with smooth joint movement. . . .

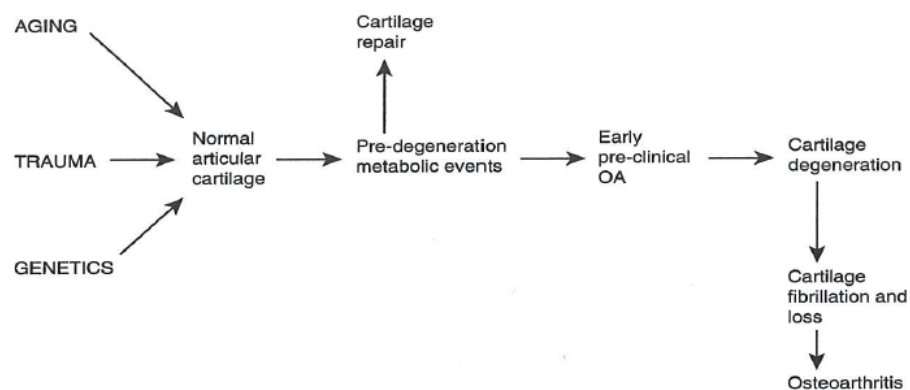
As the disease progresses, more cartilage breaks down. The joint space narrows, and eventually, instead of effortlessly gliding over one another, bones rub on uncushioned bones, making joint motion excruciatingly painful and often totally impossible. Fortunately it usually takes many years for the process to become noticeable or to interfere with a pleasurable lifestyle.

Because osteoarthritis involves deterioration of the cartilage, the disease is often called degenerative joint disease, or DJD. Figure 3-5 schematizes the vicious cycle characteristic of osteoarthritis.

- Figure 3-5

○

FIGURE 3-5: *The Progressive Development of Osteoarthritis*

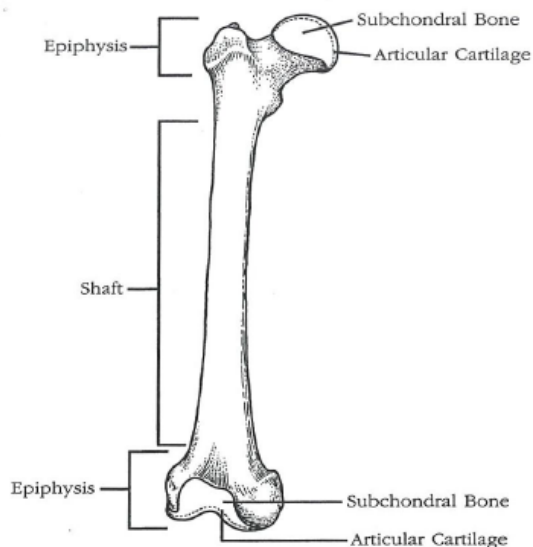


The initiating factor for osteoarthritis may be one of many things, including trauma, aging, or genetic predisposition. There is an initial breakdown of the extracellular matrix, to which the chondrocytes will respond. These cells will attempt to repair the damaged cartilage, and the repair may be successful. The attempts at repair may, however, be unsuccessful, and the incremental breakdown will become overwhelming. Ultimately the cartilage will undergo dramatic degeneration leading to osteoarthritis. These events may occur over many years.

- Figure 3-I

○

FIGURE 3-I: *Schematic View of a Long Bone*



The Shaft: The shaft is the central portion of the bone, consisting of relatively unbending, dense connective tissue providing rigidity.

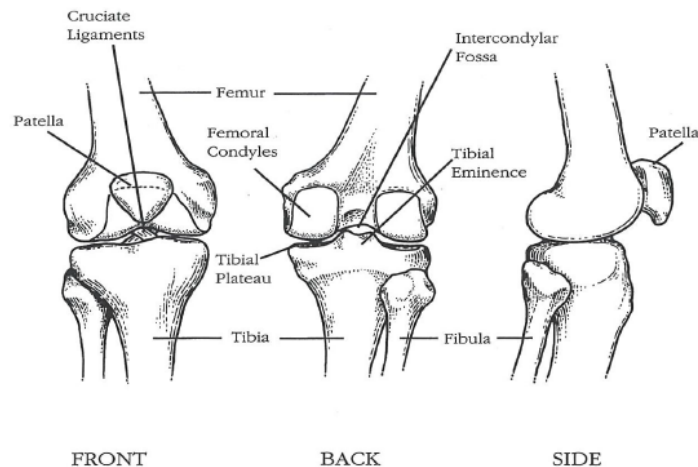
The Epiphysis: Growth, during the first fifteen to twenty years of life, takes place in the epiphyses, the ends of the bone.

Subchondral Bone: Directly under the cartilage is a layer of subchondral ("under cartilage") bone that is more porous and is replaced more frequently by new bone than the more highly calcified bone of the shaft. Upon impact subchondral bone can absorb some of the stress. Subchondral bone becomes less metabolically active with age, a fact that might contribute to the osteoarthritic process.

Articular Cartilage: The arrangement of the collagen and proteoglycan fibrils within the cartilage is such that they distribute the stress created by movement. The stress is highest in the weight-bearing joints, such as the hips and knees, but can be considerable in other, smaller joints.

- Figure 10-I

○



The knee joint connects the bottom end of the femur and the top of the tibia. At its lower extremity the femur divides into two rounded knuckles called the *femoral condyles*: the medial femoral condyle and the lateral femoral condyle. The rounded, depressed space between the two condyles of the femur is the intercondylar fossa.

The *tibia* (shinbone) ends in the *tibial plateau*, consisting of two shallow plates separated by two bony upward projections forming the *tibial eminence*, which moves with the *intercondylar fossa*.

A small, round bone, the *patella* (kneecap), fits neatly in a groove at the end of the femur and is the third bony component of the knee joint. The patella participates in knee motion, increasing the efficiency of the thigh muscles (quadriceps), which extend and straighten the knee. Stability in the knee is conferred by strong ligaments and muscles.

Two of the ligaments pass through the middle of the knee. Because they cross one another they are called the cruciates—from the Latin word *crux*, for “cross.”

- Page 146-148

- The top of the tibia and the bottom of the femur are cushioned by glossy, shiny, “glasslike” hyaline cartilage. In this as in other joints, cartilage serves as a shock absorber. It also provides a gliding surface with minimal friction, which enables the

joint to function smoothly and effortlessly. Osteoarthritis and rheumatoid arthritis attack this cartilage, causing it to pit, buckle, and gradually erode away.

- Page 153

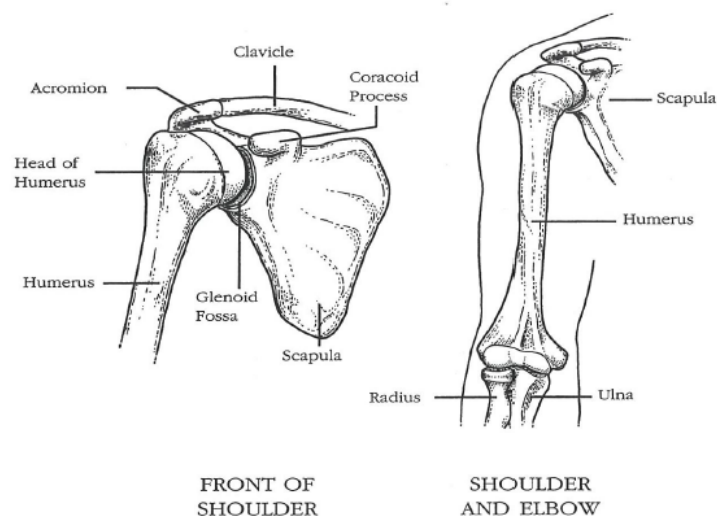
- **Diagnosis**

Treatment, including any surgical intervention, should always be preceded by a thorough diagnostic evaluation. This comprises a medical history of the complaint, a thorough physical examination, a laboratory workup, X rays or other imaging techniques (such as MRI), and a functional evaluation.

- Figure 12-I

-

FIGURE 12-1: *The Shoulder*



The shoulder or shoulder girdle is a conglomeration of four joints that attach the arm to the trunk. The principal bones involved are the humerus (upper arm bone), the scapula (shoulder blade), and the clavicle (collarbone). The glenohumeral joint, which often develops osteoarthritis, is formed by the upper end of the humerus and the glenoid cavity of the scapula. It is a ball-and-socket joint like the hip, except that the socket—the glenoid fossa—is much shallower than the acetabulum.

- Page 195-196

- Diagnosis is complicated since the shoulder develops many aches and pains, most of them not related to arthritis. . . .

An X ray confirms a diagnosis. Early osteoarthritis is marked by joint space narrowing. As the disease progresses, the smooth hyaline surface is pitted, becoming increasingly uneven. More advanced disease is characterized by osteophyte formation. Eventually the shoulder cartilage wears out, and bone rubs on bone.

- Page 233

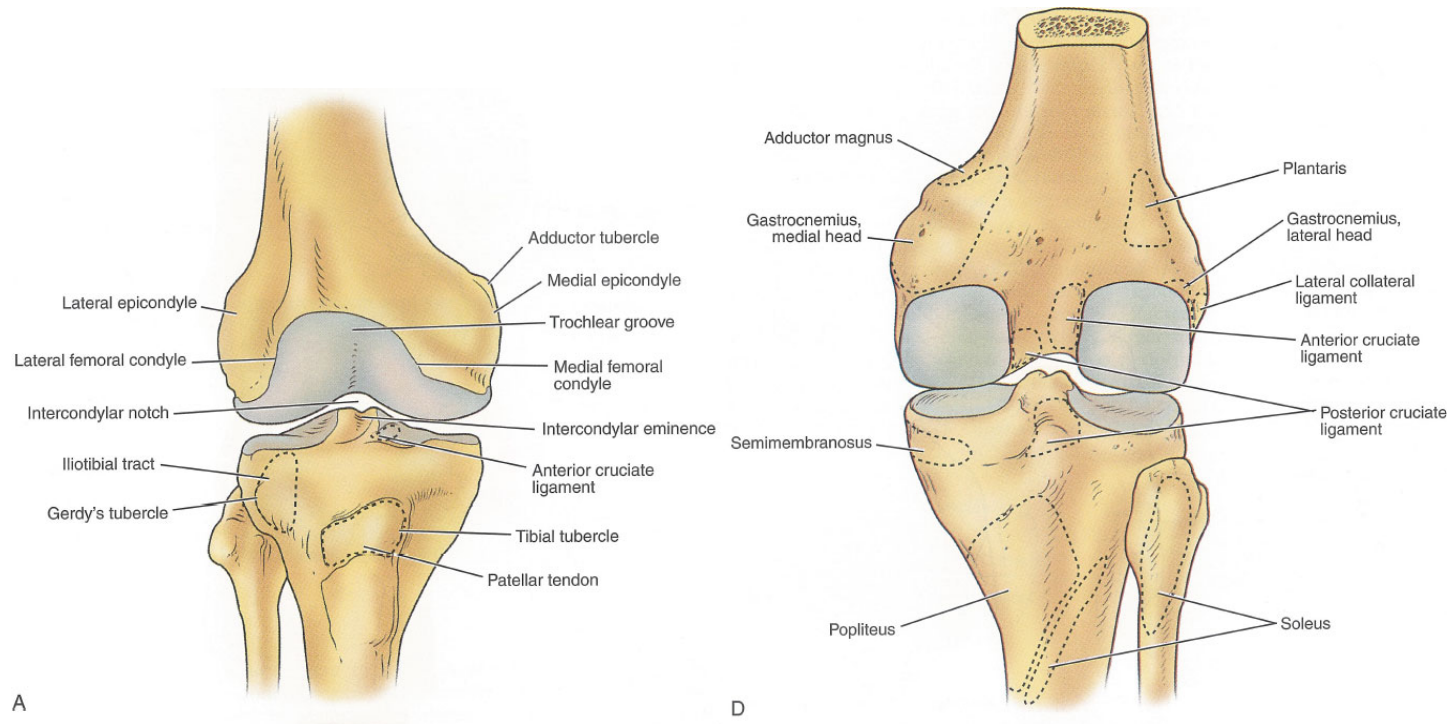
- Newer imaging techniques produce sharper, three-dimensional images. Computerized axial tomography (CT scan) is particularly good in providing details of bony tissue. Magnetic Resonance Imaging (MRI), which is even more expensive than a CT scan, provides good images of soft tissue.

A person of ordinary skill in the art would have been motivated to combine the teachings of OSTEOARTHRITIS HANDBOOK with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that OSTEOARTHRITIS HANDBOOK teaches the anatomical conditions of a joint that can be taken into account when designing tools for total joint arthroplasty. Specifically, OSTEOARTHRITIS HANDBOOK teaches the location and condition of healthy articular cartilage. *See, e.g.*, Figures 3-I and 10-I. Additionally, OSTEOARTHRITIS HANDBOOK teaches the condition of cartilage in the advanced stages of osteoarthritis, which is when it is most often clinically indicated for patients to undergo total knee arthroplasty. *See, e.g.*, Page 36-37 ("The smooth cartilage surface may become pitted and frayed. Eventually the cartilage may lose some of its ability to hold fluid, thereby becoming less able to withstand loading. This irregular joint surface may begin to interfere with smooth joint movement. . . . As the disease progresses, more cartilage breaks down. The joint space narrows, and eventually, instead of effortlessly gliding over one another, bones rub on uncushioned bones, making joint motion excruciatingly painful and often totally impossible."). Further, many of the references identified in Defendants' Invalidity Contentions are directed to tools for total joint arthroplasty, including total knee arthroplasty, thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint arthroplasty, including the presence of cartilage, into account when designing patient-specific tools for total joint arthroplasty. Choosing a cartilage surface in lieu of or in addition to a subchondral surface would also be a design choice as there are a finite number of choices for engagement. To the extent not already disclosed, any resulting modification would merely require combining one known element with another known element to obtain a predictable result of obtaining a device tailored to a patient's cartilage surface and represent a choice from a finite number of identified, predictable solutions with a reasonable expectation of success.

iii. Insall

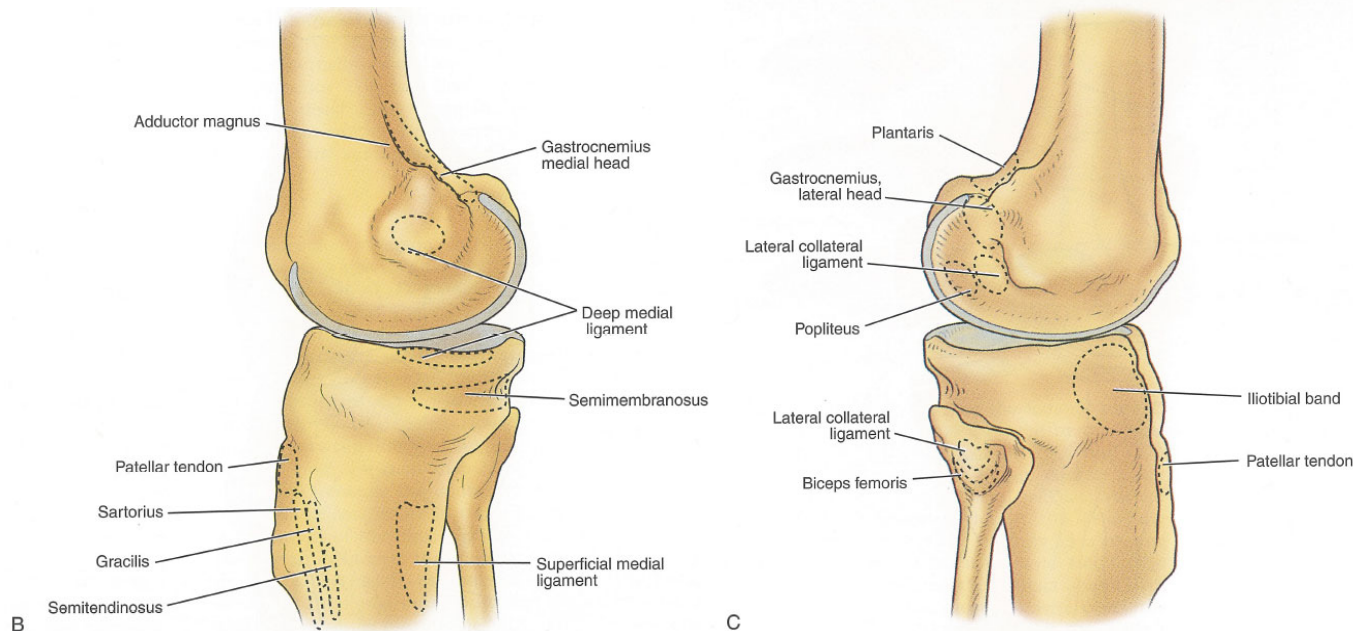
- Figures 2.8A & 2.8D

○



- Figure 2.B & 2.C

○



- Page 22

- Examination of gross specimens or arthroscopic visualization reveals normal cartilage to be a white, smooth, and firm material. Articular cartilage damage or degeneration, termed chondromalacia, can be quite readily identified (Fig. 2.14). These characteristic changes seen during arthroscopic examination have been classified by Outerbridge⁶⁴: grade 0 is normal, white-appearing cartilage; grade I is swelling or softening of an intact cartilage surface; grade II is represented by fissuring and fibrillation over a small area (<0.3 inch); grade III is the same pathological changes over a larger area (>0.5 inch); grade

IV changes represent erosion to the subchondral bone and are indistinguishable from osteoarthritis. Chondral flap tears caused by delamination of the articular cartilage may also be encountered (Fig. 2.15).

- Figure 2.15

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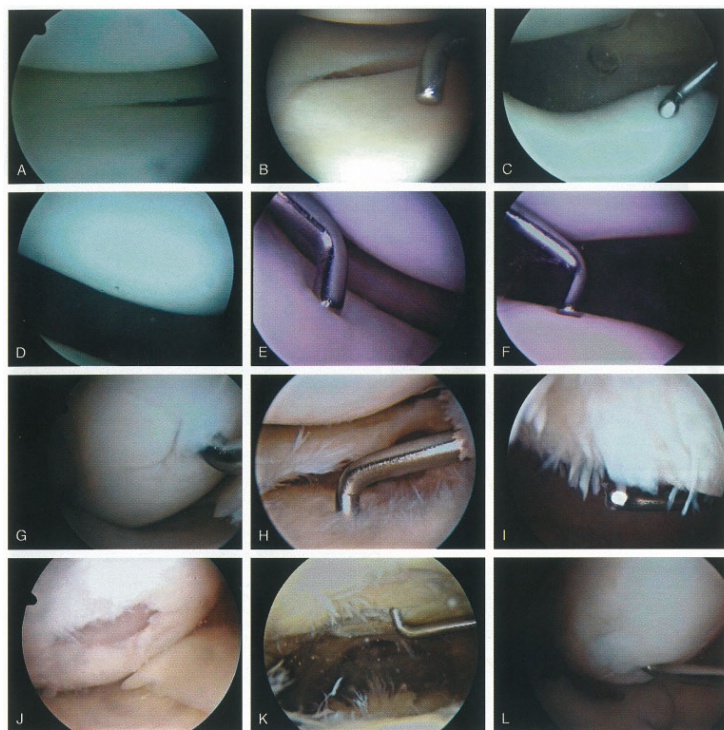


FIGURE 2.15 ➤ Arthroscopic views of articular cartilage. Normal white, smooth articular cartilage (Outerbridge grade 0) in the medial (A), lateral (B), and patellofemoral compartments (C and D). Softening of the articular surface of the lateral tibial plateau (E) and patellofemoral articulation (F) with indentation at the probe tip (Outerbridge grade 1) is noted. (G) A small fissure and fibrillation of the medial femoral condyle (Outerbridge grade 2). Extensive fibrillation of the articular cartilage involving the tibial plateau (H) and patella (I) (Outerbridge grade 3). Erosion of articular cartilage to subchondral bone involving the medial femoral condyle (J) and patella (K) (Outerbridge grade 4). Arthroscopic view of a chondral flap tear (L); the probe tip is deep to a flap of delaminated articular cartilage on the medial femoral condyle.

- Page 22

- These changes in the articular cartilage cannot be directly visualized on conventional radiographs but may be seen on magnetic resonance imaging (MRI) studies. However, even MRI is unreliable for detecting early stages of chondromalacia. These may appear as foci or areas of diffuse abnormal signal with a normal surface. Grade III or IV chondromalacia is visible as thinning, irregularity, and fissuring of the cartilage (Fig. 2.16).

- Figure 2.16

○

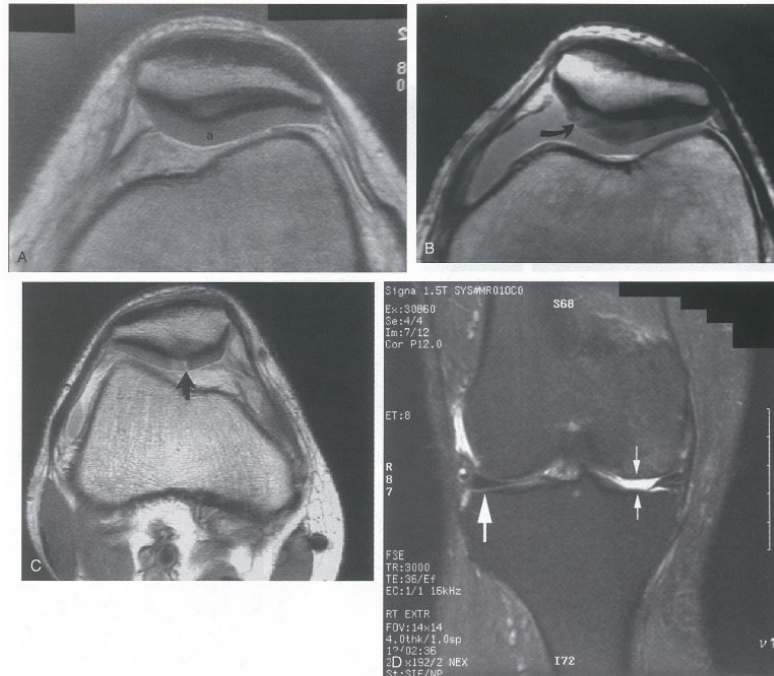


FIGURE 2.16 > A Axial magnetic resonance imaging (MRI) shows normal articular cartilage (a) on the patella facets. The cartilage has a uniform signal thickness and appearance. B, Axial MRI reveals fissuring and fibrillation of articular cartilage on the medial facet of the patella (arrow). C, Axial MRI with advanced chondromalacia of the patella. The signal irregularity extends to the subchondral bone, and a deep fissure is identified (arrow). D, Coronal MRI demonstrates complete loss of the articular cartilage of the medial compartment (thin arrows). For comparison, the gray band of articular cartilage on the lateral tibial plateau is also identified (thick band).

- Pages 122-123

- Following conventional radiography, MRI has emerged as the imaging modality of choice for evaluation of the musculoskeletal system. MRI provides a noninvasive multiplanar assessment of bones and joints with exquisite anatomic detail and superior spatial resolution and without exposing the patient to ionizing radiation.

MRI detects very subtle changes and differences in tissue characteristics, allowing earlier and more specific diagnosis of pathological processes than any other imaging modality.

- Page 125

- Although MRI is considered safe for most individuals and uses no ionizing radiation, there are specific contraindications. These contraindications are directly related to implanted internal devices or metallic clips that can either cease functioning or move when exposed to a powerful magnetic field.

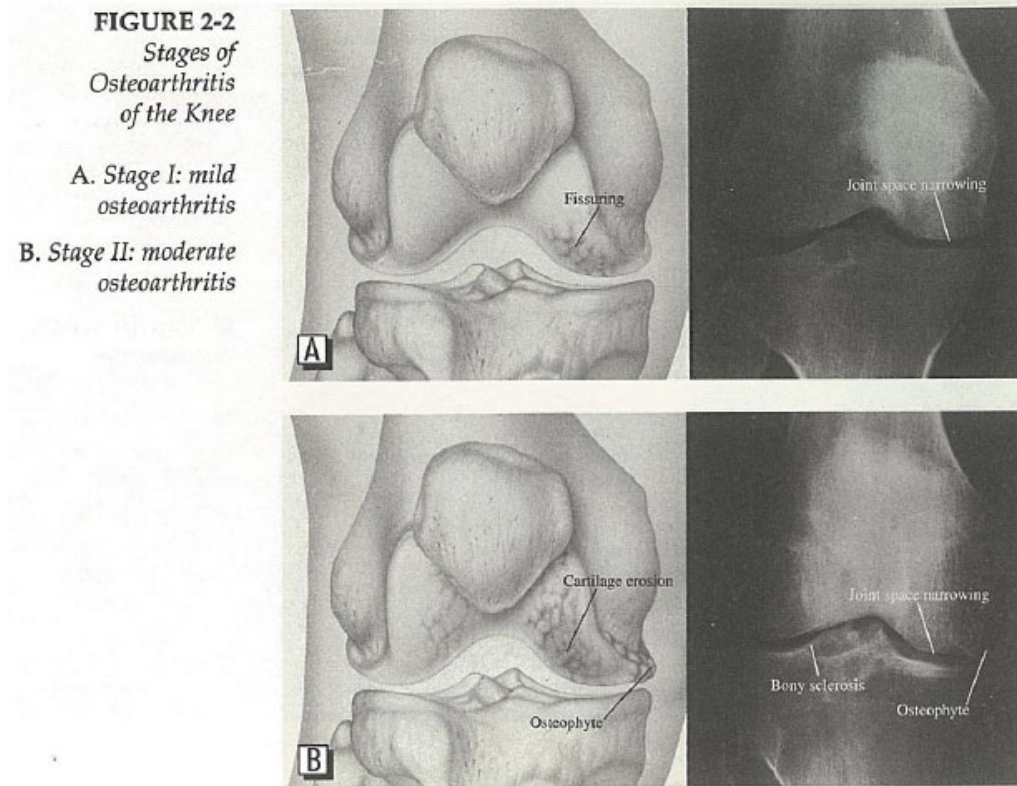
A person of ordinary skill in the art would have been motivated to combine the teachings of Insall with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Insall and many of the identified references come from the same field, knee surgery, and that Insall is focused on communicating relevant information regarding knee surgery. A POSITA would also recognize that Insall teaches the anatomical conditions of the knee that should be taken into account when conducting knee surgery. Specifically, Insall teaches the location of cartilage on a healthy knee, that damage that can occur to cartilage, and that cartilage can be imaged with MRI. Thus, a POSITA would be motivated to take this information regarding cartilage into account when designing tools for total knee arthroplasty. Choosing a cartilage surface in lieu of or in addition to a subchondral surface would also be a design choice as there are a finite number of choices for engagement. To the extent not already disclosed, any resulting modification would merely require combining one known element with another known element to obtain a predictable result of obtaining a device tailored to a patient's cartilage surface and represent a choice from a finite number of identified, predictable solutions with a reasonable expectation of success.

iv. ARTHRITIS OF THE HIP & KNEE

- Pages 12
 - Osteoarthritis is an abnormal condition that causes a joint and its surrounding structures to deteriorate to varying degrees. (See Figures 2-1 and 2-2 on the stages osteoarthritis of the hip and knee.) This degeneration in turn may cause pain and loss of function, also to varying degrees.
- Pages 13-14
 - Arthritis creates abnormalities within the structure of the joint. These abnormalities can cause the soft tissue that can cause the firm, smooth, shiny surface of the joint (the articular cartilage) to become thin and irregular. The bone under the cartilage may become very dense and stiff. Outgrowths, called osteophytes or spurs, may appear at the edge of the articular cartilage. These abnormalities within the joint cause weakness of the muscles and surrounding ligaments, joint instability, and pain.

- Figure 2-2

○



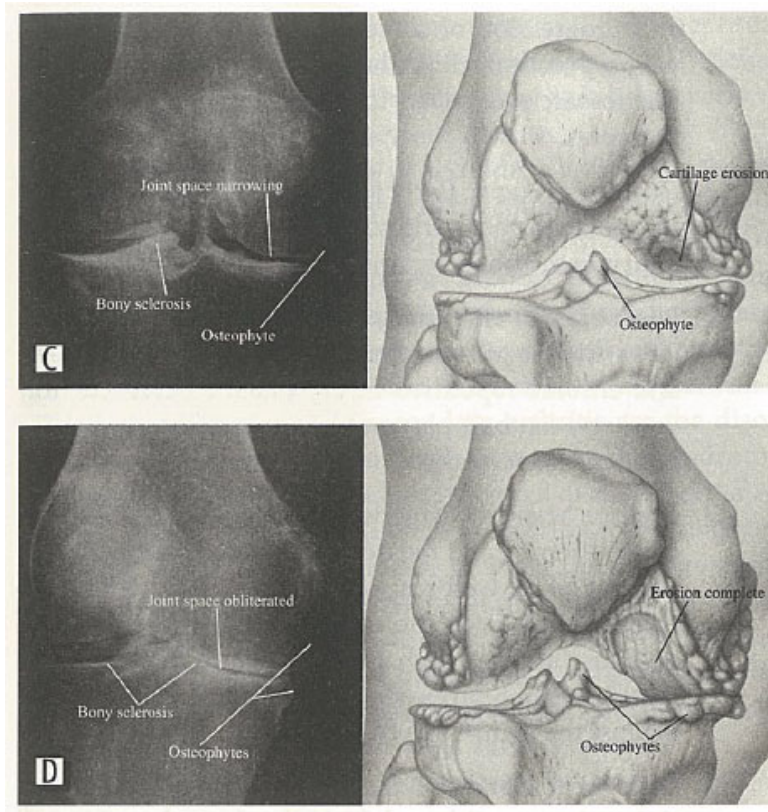


FIGURE 2-2

*C. Stage III:
moderately severe
osteoarthritis*

*D. Stage IV: severe
osteoarthritis*

- Figure 2-1

○

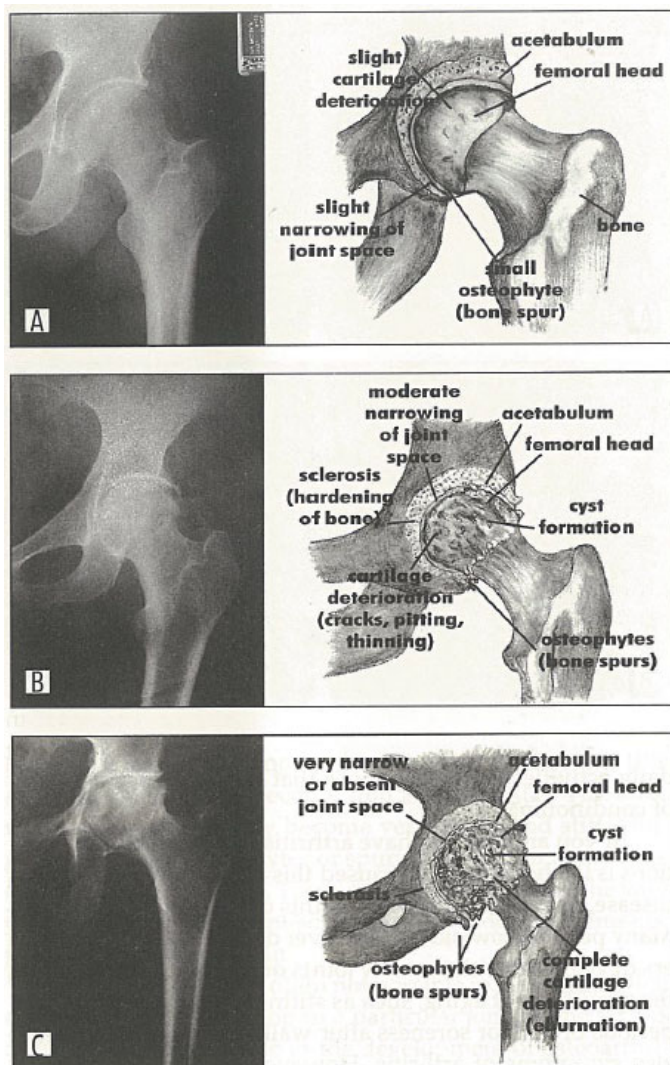


FIGURE 2-1
Stages of
Osteoarthritis
of the Hip

A. Stage I: mild
osteoarthritis

B. Stage II: moderate
osteoarthritis

C. Stage III: severe
osteoarthritis

- Page 63

- Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful.

A person of ordinary skill in the art would have been motivated to combine the teachings of ARTHRITIS OF THE HIP & KNEE with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that ARTHRITIS OF THE HIP & KNEE teaches the anatomical conditions of a joint that can be taken into account when performing total joint arthroplasty. Specifically, ARTHRITIS OF THE HIP & KNEE teaches that in the advanced stages of osteoarthritis, which is when it is most often clinically indicated for patients to undergo total knee arthroplasty, there is cartilage on the articular surfaces of the knee. *See, e.g.*, Figure 2-2; Page 63 ("Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful."). Many of the references identified in Defendants' Invalidity Contentions are directed to tools for total joint arthroplasty, including total knee arthroplasty, thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint arthroplasty, including the presence of cartilage, into account when designing patient-specific tools for total joint arthroplasty. Choosing a cartilage surface in lieu of or in addition to a subchondral surface would also be a design choice as there are a finite number of choices for engagement. To the extent not already disclosed, any resulting modification would merely require combining one known element with another known element to obtain a predictable result of obtaining a device tailored to a patient's cartilage surface and represent a choice from a finite number of identified, predictable solutions with a reasonable expectation of success.

v. Radermacher Thesis

- Page 182

- In further work, the exemplary integration and preparation of planning and manufacturing for further clinical applications is to be carried out and clinical testing is to be continued. Furthermore, the possibilities of using alternative methods for acquiring the image and geometry information required for planning and stencil production are to be examined and, if necessary, hybrid methods are to be developed. Thus, depending on the surgical problem, a combination of ultrasound imaging for the acquisition of surface geometry and bi-planar X-ray imaging for the definition of machining geometries is conceivable. Planning and referencing based on cartilaginous joint components, on the other hand, could possibly also be

based on MR image data, whereby soft tissue structures in particular, which can be better differentiated in MR image data, such as muscle and tendon attachments, could be included in the planning. For this reason, the merging of CT and MR image data or of CT image data and standardized anatomical and biomechanical models should also be considered.

- Page 5

- In addition, magnetic resonance imaging is used for the early detection of bone marrow necrosis, the assessment of intraosseous tumors, and the visualization and differentiation of muscles, ligaments, tendons, and articular cartilage [Hipp and Grading 1988].

- Pages 55-56

- 4.1 The concept of customized templates

The aim of the development is, on the one hand, to support the planning of surgical corrective procedures on bone structures by computer-aided preprocessing and reconstruction of three-dimensional CT image data, by linking additional information specific to the procedure or implant, and by additional tools for analysis and simulation. On the other hand, the preoperative planning information is to be stored and processed, in such a way, that intraoperative processing of the real bone structure, with conventional processing tools, is possible with corresponding accuracy.

The basic idea of the developed solution approach is to supplement the information of the exact spatial position, relative to the bone, which is missing from the conventional standard templates, based on individual CT image-based bone geometry model data, as well as the individual spatial planning of the surgeon. This is intended to exploit the advantages of conventional processing devices, to increase their accuracy, but also to create implementation aids for orthopedic procedures for which no processing devices are currently available.

Individual templates will be constructed on a patient-specific basis, using 3D reconstructions of preoperative CT image information. In addition to the surgical processing geometries, attachment areas of the template on the natural surface of the bony structure, which are conventionally accessible to the surgeon, are also defined as reference structures.

These segments of the individual bone surface geometry, reconstructed from CT data, are then structurally incorporated preoperatively into a corresponding template element under computer control, in such a way, that a clearly defined positive fit of the template, on the corresponding natural surface of the bone, is ensured and a planned position can thus be retrieved

intraoperatively.* In addition, tool guides are integrated or adapted into the template elements, in position and orientation according to the planned processing geometry. . . . The solution concept is thus based on the process concept shown schematically in Figure 4-2, which is to be included in the further development and evaluation of the solution approach.

- Figure 4-1

-

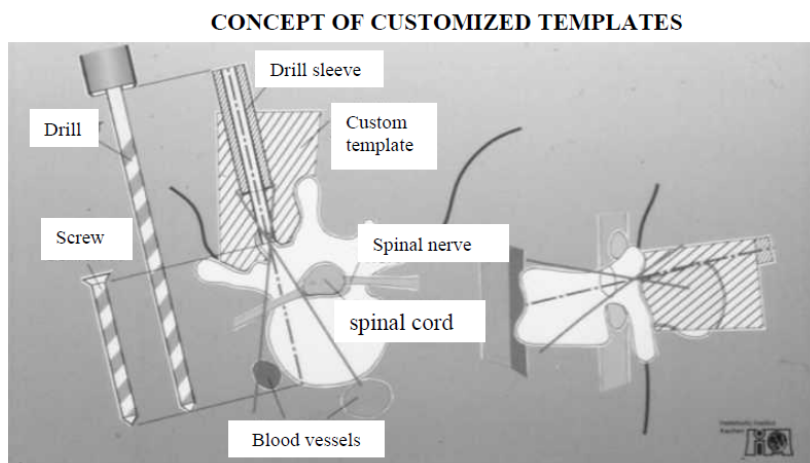


Figure 4-1: Schematic representation of the positioning of tool guides, by means of individually form-fitted reference surfaces or "contact surfaces", adapted to segments of the natural bone surface.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach patient-specific templates. *See, e.g.,* Radermacher Thesis at 3 ("Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on

individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen.”). Radermacher Thesis also teaches that when MRI is used in place of CT imaging, cartilage can be included in surgical planning of the templates. *See, e.g., id.* at 182 (“Planning and referencing based on cartilaginous joint components, on the other hand, could possibly also be based on MR image data, whereby soft tissue structures in particular, which can be better differentiated in MR image data, such as muscle and tendon attachments, could be included in the planning. For this reason, the merging of CT and MR image data or of CT image data and standardized anatomical and biomechanical models should also be considered.”). Thus, a POSITA would be motivated to include cartilage information in the patient-specific surface of an individual template. Furthermore, choosing a cartilage surface in lieu of or in addition to a subchondral surface would also be a design choice as there are a finite number of choices for engagement. To the extent not already disclosed, any resulting modification would merely require combining one known element with another known element to obtain a predictable result of obtaining a device tailored to a patient’s cartilage surface and represent a choice from a finite number of identified, predictable solutions with a reasonable expectation of success.

vi. Vomlehn

- Abstract

- A system for constructing a reference structure intended to fit flush against an anchor site of a subject is used to anchor and guide medical equipment, or used for accurate placement of fasteners into the anchor site. The present invention employs a medical imaging device (11) which acquires data of internal structures of the subject. This data is segmented (19) into discrete solid structures. These solid structures are displayed on a user interface (23) as a 3D computer model. The user then selects a structure and an anchor site on the structure which a fastener is to be positioned. The user may also interactively indicate, through the user interface, a location and orientation in which the fastener is to be inserted. A design device (25) creates a surgical guide having a mating face which fits flush against the anchor site. The guide may have pre-drilled guide holes for receiving a surgical instrument, such as a drill for drilling into the anchor site. It may have an attachment structure for attaching medical equipment. Several probe holes may also be made which receive a probe and intersect with the anchor site. Markings on the probe indicate if the mating face is flush against the anchor site.

- [0015]
 - A medical imaging means acquires medical imaging data of the subject 1 in a region including the anchor site. The user may operate a user interface to steer the medical imaging means to the proper region.
- [0016]
 - A segmentation device identifies a segmented structure being contiguous locations in the imaging data having the data values within a defined range.
- [0018]
 - A design device, which may be a conventional computer aided design (CAD) device, creates a computer model of a reference structure having a mating surface designed to fit flush with said subject's anchor site.
- [0028]
 - A subject 1 on which the procedure is to be performed, is imaged with a medical imaging device 11. Medical imaging device 11 may be a computed tomography (CT), magnetic resonance (MR), ultrasound, or positron emission tomography (PET) imaging device. Other types of medical imaging device may also be used which provide an image of internal organs of subject 1 and can provide an image of tracked targets 28.
- [0030]
 - A segmentation device 19 interacts with the volumetric data stored in data storage device 13 and determines data values within a range which may interactively be defined by user 3 via interface 17. These values are used to define a tissue type. Contiguous locations having the same tissue type are then determined. The set of all contiguous locations of the same tissue type are treated as a solid object or structure. This information may be stored in segmentation device 19 or data storage device 13.

- [0034]
 - User 3 also identifies an anchor site through user interface 17 interacting with graphics engine 21, which is a solid structure, typically bone, onto which reference structure 30 is attached.
- [0035]
 - A design device 25, which may be a computer aided design (CAD) device, interacts with user 3 through user interface 17 to 'build' a reference structure 30, as shown in Fig. 2, having a mating surface 34, designed to fit flush against the surface of the solid structure at anchor site 6 of the subject. Design device 25 may be any conventional CAD device which allows input of other models.

- Figure 2

-

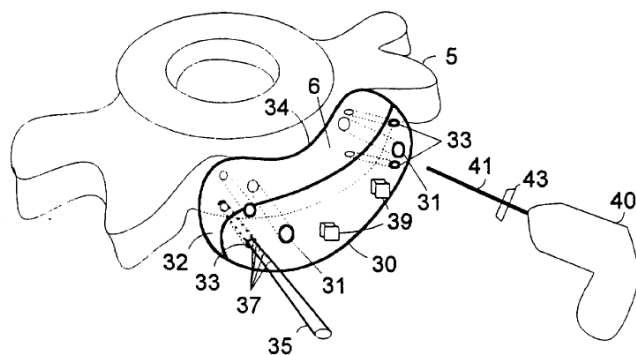


Fig. 2

A person of ordinary skill in the art would have been motivated to combine the teachings of Vomlehn with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the teachings in Vomlehn could be applied to a wide variety of orthopedic

procedures, including total knee arthroplasty. *See, e.g.*, [0001] (“The present invention relates to computer-aided construction of a reference structure to be attached to a subject and act as a guide in medical procedures.”); [0002] (“In various medical procedures, it is necessary to attach a piece of medical equipment into a solid structure of the subject.”). Furthermore, Vomlehn teaches that it can increase the accuracy of medical procedures and eliminate estimation by surgeons or the use of intraoperative imaging. *See, e.g.*, [0006] (“Typically, these pins or screws have been inserted by a surgeon who visually, or by ‘feel’, finds the approximate location where the screw or pin should be entered, and drills a hole at that location. The screw or pin is inserted into the hole.”); [0007] (“Sometimes, during surgery, two dimensional (2D) snapshots such as x-rays or magnetic resonance (MR) images may be obtained”); [0013]-[0014] (“Currently there is a need for a device which may be attached to a subject and act as a reference structure to guide instruments during medical procedures. The present invention constructs a reference structure intended to be attached to a solid anchor site of a subject.”). Thus, to the extent not disclosed, a POSITA would be motivated to apply the teachings from Vomlehn to any of the identified references.

vii. Scuderi & Tria

- Page 12-14
 - Degenerative joint disease (DJD) of the knee is the most common condition necessitating total knee arthroplasty. Radiographic findings of DJD are usually clearly evident at the time of presentation and include cartilage loss (joint-space narrowing), subchondral sclerosis and cyst formation, and osteophyte formation² (Fig. 2.11). The joint compartments are involved with the following frequency: medial > patellofemoral > lateral. . . . MR imaging, by virtue of its ability to directly image articular cartilage, synovial tissue, and subtle bone and marrow alterations, is more sensitive than conventional radiography at detecting early osteoarthritic changes and gives a more accurate assessment of the extent of disease and number of joint compartments involved^{15,16} (Fig. 2.12). MR can be used as a supplemental modality for assessing those patients with suspected early clinically symptomatic DJD and nearly normal appearing radiographs.¹⁷ It may also have a role in quantitatively monitoring progression and therapeutic response of arthritic disease.¹⁸

- Figure 2.12

○



Figure 2.12. DJD—Magnetic Resonance Imaging: Coronal fat-suppressed proton density image: There is advanced thinning of articular cartilage at the lateral compartment with absence (degeneration) of the meniscus. There is joint fluid at the lateral compartment (asterisk) outlining the subchondral bone with mild cystic changes on the femoral and tibial sides. The joint space is maintained, causing the degenerative changes to be less apparent on conventional radiographs.

A person of ordinary skill in the art would have been motivated to combine the teachings of Scuderi & Tria with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Insall and many of the identified references come from the same field, knee surgery, and that Scuderi & Tria is focused on communicating relevant information regarding knee surgery. A POSITA would also recognize that Scuderi & Tria teaches the anatomical conditions of the knee that should be taken into account when conducting knee surgery. Specifically, Scuderi & Tria teaches the effects of joint disease on cartilage and that cartilage can be imaged with MRI. Thus, a POSITA would be motivated to take this information regarding cartilage into account when designing tools for total knee arthroplasty. Choosing a cartilage surface in lieu of or in addition to a subchondral surface would also be a design choice as there are a finite number of

choices for engagement. To the extent not already disclosed, any resulting modification would merely require combining one known element with another known element to obtain a predictable result of obtaining a device tailored to a patient's cartilage surface and represent a choice from a finite number of identified, predictable solutions with a reasonable expectation of success.

H. “Anatomical” or “Biomechanical Axis” Limitations

Orienting a guide in relation to an anatomical or biomechanical axis, including as recited in the following Asserted Claims, was well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
026	15	wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.
026	52	wherein said guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis.
129	1	wherein the guide has a predetermined position relative to the patient-specific surface with a predetermined orientation relative to at least one of an anatomical axis and a biomechanical axis associated with said knee joint;
482	1	wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.
482	17	have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.
745	1	the guide having a position and orientation relative to the patient-specific surface to define a predetermined cutting path for the surgical tool that is aligned through a portion of tissue associated with the diseased or damaged joint when the patient specific surface is placed against and aligned with the corresponding cartilage surface; and
780	1	wherein the guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis associated with the joint of the patient.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Asserted Patents

- '745 Patent, 38:38-39:36; '482 Patent, 38:47-39:45; '161 Patent, 38:49-39:47; '129 Patent, 15:30-16:28; '304 Patent, 15:34-16:32; '026 Patent, 30:64-31:62; '780 Patent, 31:11-32:9
 - Computed Tomography imaging has been shown to be highly accurate for the determination of the relative anatomical and biomechanical axes of the leg (Testi Debora, Zannoni Cinzia, Cappello Angelo and Viceconti Marco. "Border tracing algorithm implementation for the femoral geometry reconstruction." Comp. Meth. and Programs in Biomed., Feb. 14, 2000; Farrar M J, Newman R J, Mawhinney R R, King R. "Computed tomography scan scout film for measurement of femoral axis in knee arthroplasty." J. Arthroplasty. 1999 December; 14(8): 1030-1; Kim J S, Park T S, Park S B, Kim J S, Kim I Y, Kim S I. "Measurement of femoral neck anteversion in 3D. Part 1: 3D imaging method." Med. and Biol. Eng. and Computing. 38(6): 603-609, November 2000; Akagi M, Yamashita E, Nakagawa T, Asano T, Nakamura T. "Relationship between frontal knee alignment and reference axis in the distal femur." Clin. Ortho. and Related Res. No. 388,147-156, 2001; Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." Med. Eng. and Phys. 24 (2002) 617-622; Lam Li On, Shakespeare D. "Varus/Valgus alignment of the femoral component in total knee arthroplasty." The Knee, 10 (2003) 237-241).

The angles of the anatomical structures of the proximal and distal femur also show a certain variability level (i.e. standard deviation) comparable with the varus or valgus angle or the angle between the anatomical femoral axis and the biomechanical axis (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." Med. Eng. and Phys. 24 (2002) 617-622). Thus, a preferred approach for assessing the axes is based on CT scans of the hip, knee and ankle joint or femur rather than only of the knee region.

CT has been shown to be efficient in terms of the contrast of the bone tissue with respect to surrounding anatomical tissue so the bone structures corresponding to the femur and tibia can be extracted very accurately with semi automated computerized systems (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." Med. Eng. and

Phys. 24 (2002) 617-622; Testi Debora, Zannoni Cinzia, Cappello Angelo and Viceconti Marco. "Border tracing algorithm implementation for the femoral geometry reconstruction." Comp. Meth. and Programs in Biomed., Feb. 14, 2000).

While 2-D CT has been shown to be accurate in the estimation of the biomechanical axis (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." Med. Eng. and Phys. 24 (2002) 617-622; Testi Debora, supra.; Lam Li On, Supra, 3-D CT has been shown to be more accurate for the estimation of the femoral anteversion angle (Kim J S, Park T S, Park S B, Kim J S, Kim I Y, Kim S I. Measurement of femoral neck anteversion in 3D. Part 1: 3D imaging method. Medical and Biological engineering and computing. 38(6): 603-609, November 2000; Kim J S, Park T S, Park S B, Kim J S, Kim I Y, Kim S I. Measurement of femoral neck anteversion in 3D. Part 1: 3D modeling method. Medical and Biological engineering and computing. 38(6): 610-616, November 2000). Farrar used simple CT 2-D scout views to estimate the femoral axis (Farrar M J, Newman R J, Mawhinney R R, King R. Computed tomography scan scout film for measurement of femoral axis in knee arthroplasty. J. Arthroplasty. 1999 December; 14(8): 1030-1).

- '745 Patent, 69:11-15; '482 Patent, 69:19-23; '161 Patent, 69:20-24; '129 Patent, 43-65-44:2; '304 Patent, 44:3-7; '026 Patent, 52:59-63; '780 Patent, 6-10
 - Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee.
- '745 Patent, 97:57-61; '482 Patent, 98:1-5; '161 Patent, 98:1-5; '026 Patent, 80:65-81:2; '780 Patent, 81:10-14
 - For example, a standard surgical cut block as described for standard implants, for example in the knee the J&J PFC Sigma system, the Zimmer Nexgen system or the Stryker Duracon system, can be connected or placed on the mold.
- ii. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018⁷

⁷ In the quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

- Pages 9-12

- Knee arthroplasty techniques have changed little since the introduction of intramedullary and extramedullary rods. Instead, improvements have been made to the orthopedic implants themselves. . . . Once the axes have been determined, the surgeon resects the damaged distal end of the femur and/or proximal end of the tibia to restore mechanical alignment to the joint. As Dr. Mayor explains, "[i]t is of the utmost importance that the distal femur and proximal tibia be cut perpendicular to the femoral and tibial mechanical axes, respectively." The distal femur and proximal tibia must also be cut at the appropriate depth to achieve proper joint spacing (e.g., not too tight and not too lax) while providing sufficient support for the implant.

- Pages 12-13

- For the last four decades (and still today), the majority of total knee arthroplasties have been performed using a rod-based system to properly align cutting guides. Rod-based systems use a combination of intramedullary and extramedullary rods to facilitate the placement of cutting guides. . . . The cutting guide includes one or more cutting paths that guide tools, e.g., a saw, that the surgeon will use to resect the femur. To ensure proper alignment, the femoral cutting guide must be placed and adjusted so the resection of the distal femur is perpendicular to the mechanical axis. Because the intramedullary rod approximates the anatomical axis, the cutting path in the femoral cutting guide must be oriented according to the preoperatively determined offset between the femoral anatomical axis and femoral mechanical axis.

- iii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

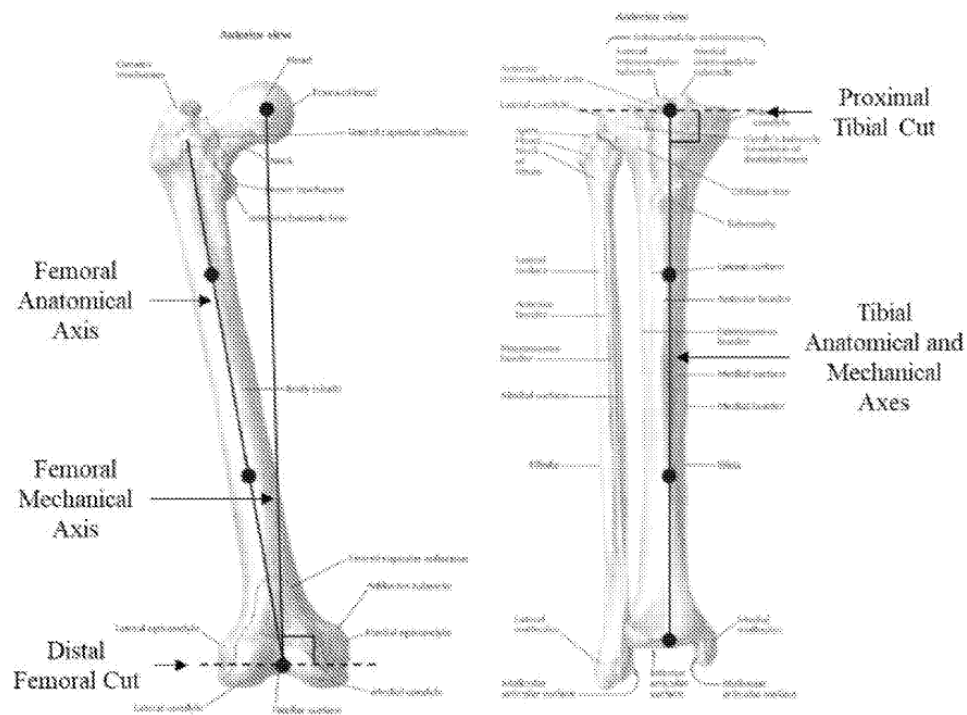
- Paragraph 25

- Once a patient is a candidate for a total knee arthroplasty, the surgeon preoperatively plans the arthroplasty. The preoperative planning involves using x-ray images¹ to determine the mechanical and anatomical axes of the femur and tibia and discern varus (bowlegged) or valgus (knock-kneed) knee deformities.² As shown in the annotated figures below, the femoral mechanical axis is the straight line that extends from the center of the femoral head (at the hip joint) to the center of the intercondylar notch (at the knee joint). The femoral anatomical axis is the straight line that extends along the inside of the shaft of the femur (diaphysis). The femoral anatomical axis is offset from the femoral mechanical axis due to the angular extension of the femoral head in the hip joint. The tibial mechanical axis is the straight line that extends from the center of the tibial plateau (at the knee joint) to the midpoint between the lateral and medial malleolus (at the ankle joint). The tibial

anatomical axis is the straight line that extends through the shaft of the tibia (diaphysis). Generally, the tibial anatomical axis closely aligns with the tibial mechanical axis.

- Page 11

○



- Paragraph 27

- The primary goals of knee arthroplasty are to relieve pain by replacing the damaged articulating surfaces, to realign the knee joint by bringing the knee joint back in line with the center of the hip joint and the center of the ankle joint, and to restore function. To do that, the distal end of the femur and the proximal end of the tibia are resected so that after the femoral and tibial implant components are implanted, the mechanical axis of the femur is again generally aligned with the mechanical

axis of the tibia. It is of the utmost importance that the distal femur and proximal tibia be cut perpendicular to the femoral and tibial mechanical axes, respectively. This ensures that the resulting post-operative knee joint is not varus (bowlegged) or valgus (knock-kneed). In other words, cutting the distal femur perpendicular to femoral mechanical axis and the proximal tibia perpendicular to the tibial mechanical axis ensures that the center of the hip joint, the center of the knee joint, and the center of the ankle joint again form a generally straight line.

- Paragraphs 37-38

- Patient-specific knee arthroplasty techniques differ from traditional knee arthroplasty techniques in several other ways as well. In addition to plain x-ray images, tomographic (CT or MRI) images of the distal femur and proximal tibia are obtained.⁴ These tomographic images are used to construct three-dimensional computer models of the distal femur and proximal tibia. The three-dimensional computer models are then used to create a surface on the cutting guide that is specific to a portion of the patient's anatomy. That is, a surface of the cutting guide will match a portion of the exterior surface of the patient's anatomy and orient the cutting guide relative to the patient's anatomy.

Regardless of which technique is used, it is still of the utmost importance to resect the distal femur perpendicular to the femoral mechanical axis and proximal tibia perpendicular to the tibial mechanical axis. The orientation of the cutting paths in the patient-specific cutting guide may be preoperatively determined from the plain x-ray images, the CT images, or the computer models. The distal femoral and proximal tibial cutting paths may then be preoperatively incorporated into the cutting guide such that when the cutting guide is placed against the patient's anatomy, the distal femoral and proximal tibial cutting paths are properly aligned perpendicular to the femoral and tibial mechanical axes without intraoperative adjustment. The resulting cutting guide thus includes a patient-specific surface that matches a portion of the exterior surface of the patient's anatomy as well as a cutting path that is aligned perpendicular to the femoral or tibial mechanical axis when the cutting guide is used.

- Paragraph 41-42

- In the mid to late 1960s, a unicondylar knee arthroplasty system was developed. This system involved implanting two femoral components and two tibial components. Again, no cutting guides were used. Unlike the first knee arthroplasty technique, the femur and tibia were resected to implant the femoral and tibial components. In particular, the distal femur and proximal tibia were resected to match the interior surface of the femoral and tibial implant components, respectively.

The resections were planned intraoperatively using dye to draw the resection lines on the femur and tibia. This unicondylar knee arthroplasty system was the first system to attempt to restore mechanical alignment to the leg.

In the mid to late 1970s, a total condylar system with unitized femoral and tibial implant components was developed. Like the unicondylar knee, the femur and tibia were resected to implant the femoral and tibial components, but unlike the unicondylar knee, the entire distal femoral surface and the entire proximal tibial surface were removed. For the first time, however, cutting guides were used to make the femoral and tibial resections. These guides were used to more accurately shape the distal femur and proximal tibia to match the interior surface of the femoral and tibial implant components, respectively. In the late 1970s/early 1980s, this total condylar system was improved by the use of intramedullary and extramedullary alignment rods. As I explained above, these rods were used, and continue to be used today, to more accurately restore mechanical alignment to the leg.

- Paragraph 42

- As I explained above, patient-specific techniques involve cutting guides that include a patient-specific surface that matches a portion of the patient's anatomy as well as a cutting path that is aligned perpendicular to the femoral or tibial mechanical axis.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught positioning a tool guide in a predetermined orientation relative to an anatomical or biomechanical axis. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that that positioning a tool guide in a predetermined orientation relative to an anatomical or biomechanical axis can improve the function and increase the longevity of the resulting implant. Furthermore, many of the Charted References are from the same field of invention, tools for joint arthroplasty.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Woolson

- Abstract

- A method is disclosed for the preoperative planning of a total knee replacement. Guide tools having guide members which are adjustable for placement on selected positions of the femur and tibia are used for locating the position of desired bone cuts defined by a cutting guide surface existing on the guide member. . . . This provides for precise placement of the guide tools during surgery and the making of accurate and precise bone cuts conforming to the selected prostheses.

- Column 1, including Lines 19-60

- Total knee replacement is a common orthopaedic surgical procedure currently performed over 150,000 times each year in the U.S. The clinical results of many operations are excellent with complete relief of pain, improvement in function, restoration of motion, and correction of deformity in over 90% of the cases. However, there are a number of cases in which failures occur following the knee replacement. One of the most important causes for failure of the procedure is from prosthesis component loosening because of unbalanced loading of the tibial component caused by improper knee joint alignment. Because of this fact, all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result.

- Column 4, Lines 7 - Column 5, Line 8

- Referring initially to FIGS. 1, 2A and 2B, selected positions on the bones of interest, in this case the femur and tibia, are identified. In this instance it is important that the knee prostheses be positioned on, and for relative rotation about, an axis perpendicular to the mechanical axis of a femur 10 and a corresponding tibia 12. A mechanical axis 14 extends through the midpoint 16 of the femur head. Axis 14 also extends through midpoint 18 of the distal femur. During the knee replacement surgical procedure, it will be necessary to resection the medial and lateral condyles of the distal femur by cutting along a line 20 which is perpendicular to axis 14.

The proximal end of tibia 12 will be resectioned along a cut plane identified by the dashed line 22 in FIG. 2B. The line of this cut must be perpendicular, or slightly angled as will be discussed subsequently, relative to a mechanical axis 24 of the tibia. Axis 24 is defined by the midpoint 26 of the proximal tibia and the midpoint 28 of the ankle joint.

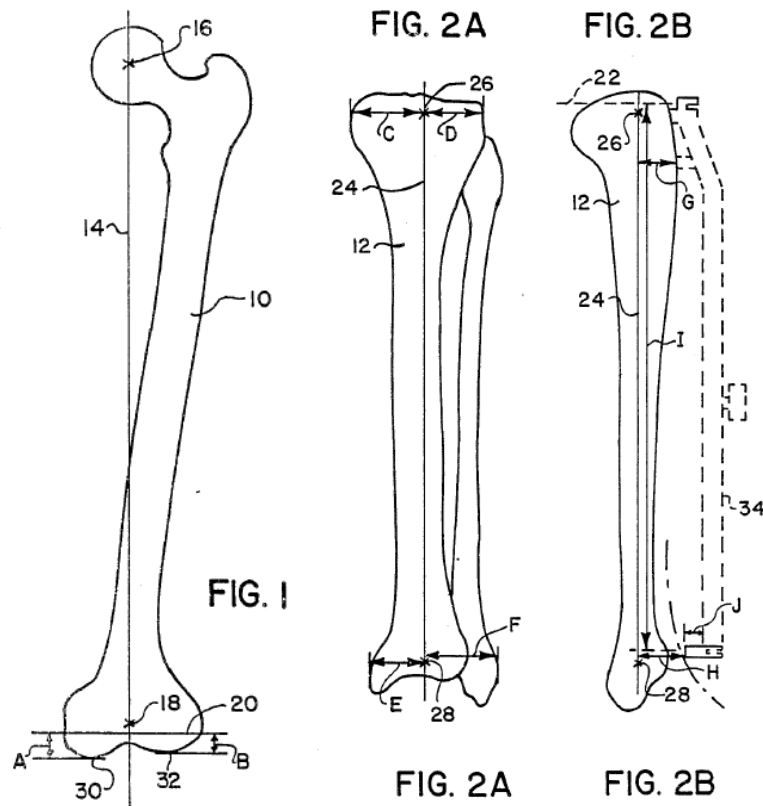
The mechanical axes of the femur and tibia in two planes can be graphically determined by identification of the 3D coordinates derived from the CT image data by identification of the positions of the midpoints of the femoral head, the distal femur, the proximal tibia and the ankle joint in the coronal and sagittal planes. Further, the 3D spatial location of the most distal projections of the medial and lateral femoral condyles 30, 32, respectively, are found in the coronal plane image, as shown in FIG. 1. The distance from each of these points to distal femoral cut line 20 is also determined. These are represented, respectively, by distances A and B. This gives the proportions of bone from the medial and lateral condyles which are to be resected to produce a distal femoral cut along line 20. As will be seen, the plane represented by line 20 in FIG. 1 is also perpendicular to the anterior femoral cortex which, in the sagittal plane, is parallel with mechanical axis 14. The remainder of the femoral bone cuts, as will be described, are customized to the specific prosthesis, and ligamentous balancing of the new knee joint is done in a routine manner.

As will be seen, the tibial cutting guide includes gauge members positioned to contact opposite sides of the proximal tibia and, with an allowance for skin depth, the lateral and medial ankle protusions. More specifically, tibial mechanical axis 24 in the coronal and sagittal planes, as seen in FIGS. 2A, 2B, is graphically depicted and the distances from this line are found to the medial cortex (distance C) and to the lateral cortex (distance D) of the proximal tibia. Also the distance from mechanical axis 24 to the skin surface over the medial malleolus (distance E) and to the skin surface over the lateral malleolus (distance F) are determined for alignment in the coronal plane. Further, from a representation of the tibia in the sagittal plane, the distance from the axis to the anterior cortex of the proximal tibia where the tibial cutting guide 34 contacts it (distance G) and the distance from the axis to the skin surface over the anterior aspect of the distal tibia (distance H) is determined. Further, the distance along axis 24 from cut line 22 to the position where distance H is measured, is also determined. This distance is shown as distance I.

Finally, as will be further described subsequently, the position of the base of tibial cutting guide 34 from the skin surface over the anterior aspect of the distal tibia can be varied to control the angle of cut line 22 with respect to axis 24. Thus, a distance J must be determined for producing the corresponding selected angle.

- Figures 1, 2A, 2B

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- Column 5, Line 36 to Column 6, Line 3

- From the spatial coordinates in the coronal plane derived from the scans of the femoral head and the distal femur, a femoral coronal mechanical axis line 14 is mapped out on graph paper as illustrated in FIG. 1. Distal femoral cut line 20 is drawn perpendicular to mechanical axis line 14. Measurements of the distances from line 20 to the most distal points 30, 32 on the

medial and lateral femoral condyles, respectively, are taken from the graph. The relative distances for medial and lateral condylar bone resection to create a distal femoral cut along line 20 are thus known. This bone cut is also made perpendicular to the anterior femoral cortex, and therefore, the distal femoral cut need only be planned in the coronal plane.

Planning of the proximal tibial cut is more complex, since the reference points for it must be determined in two planes preoperatively. The tibial mechanical axis 24 in the coronal and sagittal planes is determined from the coordinates of the centers of the ankle joint (point 28) and of the proximal tibia (point 26). The distances from this axis to the medial (distance C) and lateral (distance D) cortexes of the proximal tibia and to the skin over the medial (distance E) and lateral (distance F) malleolus are used for appropriate positioning of the tibial jig or cutting guide 34 in the coronal plane. It will be appreciated that any two of these distances are sufficient to align the tibial jig relative to the axis.

The direction of the proximal tibial cut in the sagittal plane will be dependent upon the particular total knee prostheses chosen. This cut may be made perpendicular to the sagittal mechanical axis, as is shown in FIG. 2B, or inclined posteriorly up to 5 or 10 degrees. The distance from the skin surface over the distal tibial plafond to the distal portion of the tibial cutting guide (distance J) determines the amount of posterior inclination of the tibial cut.

Using this preoperative planning method, the surgeon is able to determine mechanical axes 14, 24 and distances A-J. These specific bone landmarks and distances correspond for presetting the cutting guides illustrated in FIGS. 4-8, which now will be discussed. It will be appreciated that the various cutting guide adjustments which need to be made are precisely determined. The gauge members of the guides are adjusted corresponding to the determined distances. Thus, when these cutting guides are placed in position adjacent the bone to be resected, precise positioning and alignment are achieved.

- Column 6, Lines 32-49
 - As illustrated in FIGS. 6A and 6B, the distal femur condylar cuts are then made using a distal femoral cutting guide 58 placed flat on the anterior femur surface just cut and pinned into place. The proportion of the medial and lateral femoral condylar bone to be resected which was determined by the preoperative planning system is used to set this instrument. If, for example, this proportion is 2:1, or removal of twice the amount of medial femoral condylar bone as lateral femoral condylar bone, and the distal thickness of the femoral prosthesis is 8 mm, then the distal femoral cutting guide gauge member 60 is correspondingly adjustably positioned on an adjustment post 62 relative to a slit 64 defining a cut surface contour (corresponding to cut line 20). Correspondingly, the lateral femoral condyle cut is determined by positioning a gauge

member 66, which extends down across the face of the condyle, a distance B from slit 64, by adjustment along an adjustment post 68.

- Figures 6A

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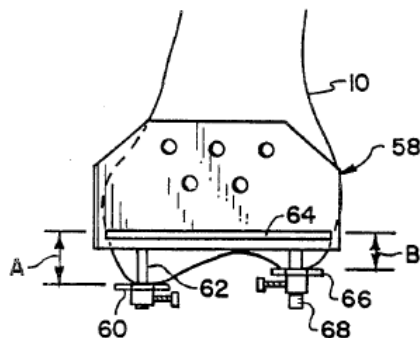


FIG. 6A

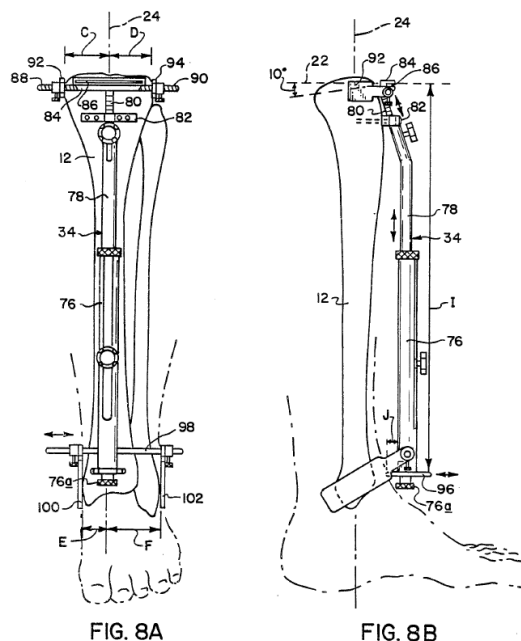
- Column 6, Line 65 – Column 7, Line

- FIGS. 8A, 8B illustrate the positioning of tibial cutting guide 34 relative to tibia 12. Cutting guide 34 includes a telescoping shaft, parallel with axis 24 as viewed in FIG. 8A, consisting of a base member 76, an intermediate shaft member 78, and a cut-positioning member 80. Each of these three members are adjustable relative to the other, as shown. Intermediate member 78 includes a brace 82 which contacts the anterior cortex of the proximal tibia. This position corresponds with the location for measuring distance G described with reference to FIG. 2B. Further, cut-positioning member 80 has a cross-arm 84 with a slit 86 defining the proximal tibial cut. Cross-arm 84 includes laterally extending adjustment bars 88,90 to which are adjustably attached corresponding gauge members 92 and 94, respectively. These gauge members are positioned relative to shaft member 80 in accordance with dimensions C and D, as described previously. At the end of base shaft member 76 opposite from intermediate shaft member 78 is a plate 96 which is adjustable relative to shaft member 76 for varying the distance of the associated end 76a of the base shaft member from the skin surface over the anterior aspect of the distal tibia, as discussed previously. End 76a is also referred to herein as a gauge member. Thus, plate 96 is adjustable for positioning the end 76a a distance J from the skin surface.

- Mounted on base shaft member 76 adjacent end 76a is a lateral adjustment bar 98 which extends to each side of shaft member 76, as shown in FIG. 8A. Each end of bar 98 has an ankle joint gauge member. A gauge member 100 is positioned a distance E for placement on the skin over the medial malleolus. The other gauge member 102 is positioned a distance F from the longitudinal axis of shaft member 76 for placement on the skin over the lateral malleolus. Thus, the adjustments of the various gauge members as well as the length of the shaft members result in cutting slit 86 being aligned perpendicular to mechanical axis 24. Thus, cutting guide 34 is aligned precisely relative to the tibia.
- The posterior inclination of the tibial bone cut is determined by the design requirements of the particular prosthesis. Adjustable plate 96 on shaft end 76a, as has been discussed, is set at a distance which will result in the desired posterior inclination of the angle of proximal tibial bone cut defined by slit 86. It is sufficient, to align tibial cut line 22 below the most deficient tibial plateau as determined by the CT scan representations. Cutting guide 34 is then stabilized in the proximal tibia by pins shown in dashed lines in brace 82. The bone cut is made along cut line 22 by passing a saw 56 through slit 86.

- Figures 8A, 8B

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A person of ordinary skill in the art would have been motivated to combine the teachings of Woolson with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Woolson comes from the same field of invention as many of the references identified in the Defendants' Invalidity Contentions and teaches tools for total knee arthroplasty similar to many of the references identified in the Defendants' Invalidity Contentions. Additionally, Woolson teaches that proper alignment of a prosthesis relative to a mechanical axis is a factor in the long-term result of a total knee arthroplasty and discloses a preoperative planning method and tools designed to place a prosthesis in proper mechanical alignment. *See, e.g.*, Woolson at 1:26-36 ("One of the most important causes for failure of the procedure is from prosthesis component loosening because of unbalanced loading of the tibial component caused by improper knee joint alignment. Because of this fact, all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which

correspondingly is highly likely to produce a successful long-term result.”); 1:8-13 (“This invention relates to a method for preoperative planning of surgery. More particularly, it pertains to a method of preoperative planning of a bone cut and joint replacement using radiant energy scan imaging to determine the position of a bone-cut-defining guide relative to the bone to be cut.”). Thus, to the extent not already disclosed, a POSITA would be motivated to combine the teachings of Woolson with any of the references identified in Defendants’ Invalidity Contentions and design at least one guide that has a predetermined orientation relative to an anatomical or a biomechanical axis of a patient.

As a further example, Woolson teaches that it can be “necessary” to align cutting paths so that they are perpendicular to the mechanical axis, and that doing so improves long-term results. Woolson at 1:26-36, 2:50-59, 4:7-26, Figs. 1, 2A-B. For instance, as the Board previously found (IPR2017-00115, Paper 33 at 43-44), Woolson itself provides the reason to combine:

One of the most important causes for failure of the [knee replacement] procedure is from prosthesis component loosening because of unbalanced loading of the tibial component caused by improper knee joint alignment. Because of this fact, all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result. Woolson, 1:26-36.

As the Board recognized, “Woolson explains that it is necessary to align the reconstructed knee with respect to the mechanical axis, to ensure proper knee-joint alignment over the long term.” IPR2017-00115, Paper 33 at 44 (citing Woolson, 1:26-36, 2:50-55). Woolson further teaches reference to the mechanical axis. Woolson, 4:9-26; *see also* IPR2017-00115, Paper 1 at 39-43 (petition explaining why Woolson renders a similar limitation obvious) As a result, it would have been obvious to align cutting or drilling guides relative to one or more mechanical or anatomic axes in light of Woolson’s disclosures so as to improve the quality of the surgery and the long-term stability of the implant. Combining Woolson with known guides disclosed in identified references would merely involve using a technique that has been employed to improve one knee arthroplasty procedure to improve a similar procedure with a predictable result. Thus to the extent not disclosed, a POSITA would be motivated to align a tool guide relative to a mechanical or anatomical axis to assure proper knee-joint alignment over the long term.

ii. Krackow

- Page 94

- At least two different alignment schemes are widely, used by total knee arthroplasty surgeons today. The intention here is not to argue the merits and drawbacks of each, but rather to present them and to describe them so that one can understand better the alignment goals that are before him in either system.

- Pages 94-95

- **Classical Arthroplasty Alignment**

The first alignment system considered is that referred to here as classical arthroplasty alignment. In such a system the goal is to create a prosthetic joint line perpendicular to the reconstructed mechanical axis. Such an arrangement is shown in Figure 4-8. It should be immediately obvious that the tibial cut in such a system is made perpendicular to the tibial shaft as this shaft axis coincides with the mechanical axis.

The distal femoral cut in such a system is made perpendicular to the femoral portion of the mechanical axis, or femoral mechanical axis, and, at the same time, has an orientation with respect to the femoral shaft axis, which differs by the indicated angle of β i.e., the same amount as the proper tibiofemoral angle. One can determine this angle by simple measurement on an AP x-ray film of the femur and is probably well advised to compare this measurement to the angle of distal femoral cut built into a given instrumentation system. As mentioned, in my own hospital radiology department, we typically measure β to be 6 degrees. If one is using instruments designed to achieve classical total knee arthroplasty alignment, and if these were configured to lead to a consistent 7- or 8-degree femoral cut, then one might expect a small tendency to valgus overcorrection.

- Figure 4-8

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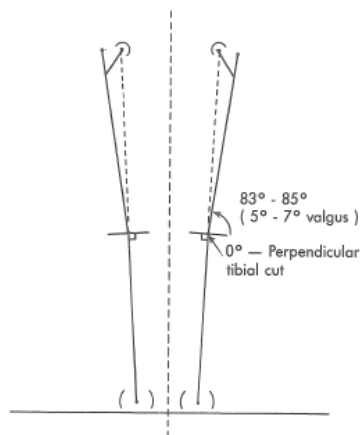


FIGURE 4-8

Classical arthroplasty alignment. Distal femoral cut is perpendicular to femoral mechanical axis. Equal to lateral angle of 83 to 85 degrees relative to shaft, known as 5 to 7 degree valgus femoral cut. The tibial resection is at 0 degrees, or perpendicular to tibial shaft axis.

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- **Anatomic Arthroplasty Alignment**

The second alignment system in use, somewhat less popular, might be called anatomic alignment. Here, the stated goal is reproduction of the joint line angulation with respect to the mechanical axis so that the joint line, in the frontal plane at least, is parallel to the ground during two-legged stance, with the feet approximated and parallel to the ground during gait.

Achievement of this type of alignment requires the performance of proximal tibial and distal femoral cuts as outlined in Figure 4-9. The cut at the upper tibia is not perpendicular to the tibial shaft axis but, instead, differs by the indicated angle θ , which is the same as the inclination of the mechanical axis during the position of examination. This angle is typically 2 to 3 degrees. To recreate a proper tibiofemoral angle leading to a mechanical axis that is centered through the joint, it is

necessary to perform a distal femoral cut equal to the angle $\beta + \theta$. It is convenient to speak of the distal femoral cut as being $\beta + \theta$ valgus angulation, while the proximal tibial cut has a varus angulation of θ degrees. When the prosthetic joint surfaces are approximated, the “algebraic” sum of these two angles results in a tibiofemoral angle of β , which is the first condition of proper knee alignment.

- Figure 4-9

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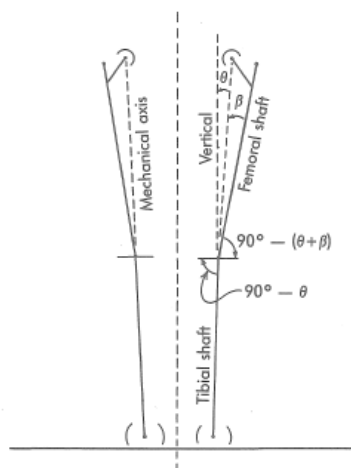


FIGURE 4-9

Anatomic alignment. Distal femoral cut is made at angle laterally, relative to femoral shaft of $90 - (\theta + \beta)$, which equals approximately 80 to 82 degrees. Relative to femoral mechanical axis, angle is 90 minus θ , or 87 to 88 degrees. Cut at tibia has internal, medial angle, which is also equal to 90 minus θ .

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- Summarizing briefly, cuts in the classical arrangement are 0 degrees on the proximal tibia and β , or approximately 6 degrees valgus at the distal femur, whereas in the “anatomic” system the distal femoral cut is $\theta + \beta$, typically 2 to 3 degrees plus 6 degrees, or 8 to 9 degrees valgus, and the proximal tibial cut is 2 to 3 degrees varus. Both yield the same tibiofemoral angle but produce a slightly different joint line orientation (Figure 4-10).

- Figure 4-10

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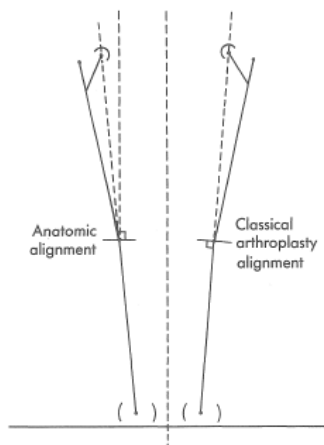


FIGURE 4-10

Anatomic and classical arrangements are contrasted. Same tibiofemoral angle has been produced because tibial shaft axis lies on projection of femoral mechanical axis. Joint line orientation differs typically by 2 to 3 degrees.

- Page 119

- Understanding these angles and having drawn them accurately on preoperative x-ray films is helpful when it is necessary intraoperatively to judge the accuracy of instrument placement. Regardless of the ultimate depth or thickness of a distal femoral or proximal tibial cut, the angular orientation selected by the instrumentation system should be leading one to a bone resection situation that resembles what was drawn and was predicted on the planning x-ray films.

- Page 96

- **Sagittal Plane Orientation**

The issue of proper joint line orientation in the sagittal plane will be discussed briefly. In the classical sense, the cut was made perpendicular to the tibial shaft axis viewed from the side. More recently, instrumentation systems and surgical

techniques, independent of instrumentation systems, have sometimes sought the creation of a posteriorly sloping joint line, ranging from a 2- or 3-degree slope to as much as a 10-degree or more posterior slope. This slant should not, in itself, alter the varus-valgus angulation in the frontal plane, which is our main consideration in this section. Arguments for and against performing a posteriorly sloping cut range from preservation of best subchondral bone to concerns over the presence of a sloped joint in the absence of an anterior cruciate ligament.

A person of ordinary skill in the art would have been motivated to combine the teachings of Krackow with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Krackow teaches alignment techniques for instruments for total knee arthroplasty and many of Defendants' identified references teach tools for total knee arthroplasty, thus, the references come from the same field of invention. Additionally, Krackow teaches two alignment systems, relative to a mechanical axis and relative to an anatomic axis. Krackow teaches the purpose of the alignment system is ensure that a prosthetic joint line is of a predetermined angle relative to a selected mechanical axis or anatomic axis. *See, e.g.*, Krackow at 94-95 ("The first alignment system considered is that referred to here as classical arthroplasty alignment. In such a system the goal is to create a prosthetic joint line perpendicular to the reconstructed mechanical axis"); 95 ("The second alignment system in use ... might be called anatomic alignment. Here, the stated goal is reproduction of the joint line angulation with respect to the mechanical axis so that the joint line, in the frontal plane at least, is parallel to the ground during two-legged stance, with the feet approximated and parallel to the ground during gait."). Krackow further teaches the types of cuts needed to achieve the stated goals of each alignment system, which involves the cuts be made at a predetermined angle relative to a mechanical axis (*e.g.*, 90 degrees) or an anatomic axis. *See, e.g., id.* at 94-96, 119. Furthermore, Krackow teaches that axial alignment should be a leading consideration of a surgeon during total knee arthroplasty. *See, e.g., id.* at 119 ("Understanding these angles and having drawn them accurately on preoperative x-ray films is helpful when it is necessary intraoperatively to judge the accuracy of instrument placement. Regardless of the ultimate depth or thickness of a distal femoral or proximal tibial cut, the angular orientation selected by the instrumentation system should be leading one to a bone resection situation that resembles what was drawn and was predicted on the planning x-ray films."). Thus, to the extent not disclosed, a POSITA would be motivated to align a tool guide relative to a mechanical or anatomical axis.

iii. Techiera

- Column 1, Lines 30-54
 - In general, it is necessary to determine a number of positioning pin locations, form a number of flat surface cuts, and carry out a soft tissue balancing procedure. Numerous specially aligned cuts at the bone ends are necessary in order to install the

prosthetic components with correct spacing, alignment and tensioning to prevent improper kinematics from arising as the joint rotates in use, and to avoid the occurrence of accelerated wear patterns or possible joint dislocation.

The bone cuts made to effect the placement and orientation of the femoral component of the prosthesis determine and form the joint gaps in extension and flexion. The size and shape of these two gaps affect final bone orientation as well as joint tensioning and clearances. The femur must be so oriented, with respect to the cut surfaces defining the prosthesis fit, so as to satisfy numerous constraints. With respect to their effect on final orientation, the flexion gap is related to internal/external orientation of the femur, while the extension gap is related to the varus/valgus orientation of the femur.

Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur, while in flexion the joint gap is such as to place the femoral component in either neutral or external rotation to assure proper patellar tracking with the femoral component.

A person of ordinary skill in the art would have been motivated to combine the teachings of Techiera with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Techiera teaches cutting the femur so that in extension the joint gap is perpendicular to the mechanical axis of the femur. *See, e.g.*, Techiera at 1:50-52 ("Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur,"). Furthermore, Techiera teaches that this alignment technique can affect the kinematics of the installed prosthesis. *See, e.g., id.* at 1:30-38 ("In general, it is necessary to determine a number of positioning pin locations, form a number of flat surface cuts, and carry out a soft tissue balancing procedure. Numerous specially aligned cuts at the bone ends are necessary in order to install the prosthetic components with correct spacing, alignment and tensioning to prevent improper kinematics from arising as the joint rotates in use, and to avoid the occurrence of accelerated wear patterns or possible joint dislocation."). Thus to the extent not disclosed, a POSITA would be motivated to align a tool guide relative to a mechanical or anatomical axis.

iv. Jazrawi et al.

- Page 764
 - Figgie et al [7,8] outlined criteria for proper axial alignment in TKA and concluded that component rotation was an important factor. Although axial and rotational alignment are recognized as critical factors influencing TKA outcome, only axial alignment has been studied extensively because, in contrast to rotational alignment, axial alignment can be measured readily from standing long-leg radiographs [2,7–22].

- Page 761

- Patellofemoral complications (eg, patella subluxation or dislocation, patellar clunk, wear or loosening of the patellar component, and patella fracture) are the most common complications after total knee arthroplasty (TKA), occurring in 30% of cases [1,2]. Poor patella tracking or dislocation can be the result of malrotation of the tibial or femoral components (or both), an excessively tight lateral retinaculum, improper patellar component positioning, patellar component loosening, improper axial orientation of the tibial and femoral components, or an *overstuffed* joint (ie, increased thickness of the patella bone–component construct) [2]. Malrotation also causes rotational incongruity between femoral and tibial components, resulting in increased contact stresses along the tibia during flexion [3]. Although most of these causes, including improper axial alignment, can be determined from plain radiographs or physical examination, implant rotational malalignment cannot.

A person of ordinary skill in the art would have been motivated to combine the teachings of Jazrawi et al. with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Jazrawi et al. is from the same field of invention as many of the identified references—total knee arthroplasty. Furthermore, Jazwari et al. teaches that its approach aids proper patella function. *See, e.g.*, Jazwari et al. at 761 (“Patellofemoral complications (eg, patella subluxation or dislocation, patellar clunk, wear or loosening of the patellar component, and patella fracture) are the most common complications after total knee arthroplasty (TKA), occurring in 30% of cases [1,2]. Poor patella tracking or dislocation can be the result of malrotation of the tibial or femoral components (or both), an excessively tight lateral retinaculum, improper patellar component positioning, patellar component loosening, improper axial orientation of the tibial and femoral components, or an *overstuffed* joint (ie, increased thickness of the patella bone–component construct) [2].”). Additionally, a POSITA would be motivated to combine the teachings of Jazwari et al. with any of the Defendants’ identified references because Jazwari et al. teaches that the axial alignment is a well-recognized concept in the art. *See, e.g., id.* at 764 (“Although axial and rotational alignment are recognized as critical factors influencing TKA outcome, only axial alignment has been studied extensively because, in contrast to rotational alignment, axial alignment can be measured readily from standing long-leg radiographs [2,7–22].”) Thus to the extent not disclosed, a POSITA would be motivated to align a tool guide relative to a mechanical or anatomical axis to promote axial alignment of the resulting implant.

v. Eckhoff et al.

- Page 28

- Two decades ago, Coventry² and Lotke and Ecker⁸ established that axial alignment was a significant factor in determining the longevity of implants in total knee arthroplasty. Since that time, the focus has remained on axial alignment, or alignment in the coronal plane of the knee, with relatively less attention paid to rotational alignment, the alignment of components in the horizontal plane of the knee.

A person of ordinary skill in the art would have been motivated to combine the teachings of Eckhoff et al. with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Eckhoff et al. is from the same field of invention as many of the identified references—total knee arthroplasty. Furthermore, Eckhoff et al. teaches that axial alignment increases the longevity of the implanted prosthesis. *See, e.g.*, Eckhoff et al. at 28 (“Two decades ago, Coventry² and Lotke and Ecker⁸ established that axial alignment was a significant factor in determining the longevity of implants in total knee arthroplasty.”). Additionally, a POSITA would be motivated to combine the teachings of Eckhoff et al. with any of the Defendants' identified references because Eckhoff et al. teaches that the axial alignment taught is a long held practice in the art. *See, e.g., id.* Thus to the extent not disclosed, a POSITA would be motivated to align a tool guide relative to a mechanical or anatomical axis to promote axial alignment of the resulting implant.

vi. Radermacher CAOS

- Page 31

- In total knee arthroplasty accurate placement of implant components with respect to the individual mechanical axis of the leg is essential. Conventionally, modular mechanical devices corresponding to the intrinsic shape of the implant components are used to guide the osteotomies and bores for the preparation of the implant's seat. By mounting these conventional tool guide systems on an individual template as a basic customized reference, it is possible to reproduce the preoperatively planned position exactly even in the case of severely deformed bone.

- Figures 2A-B

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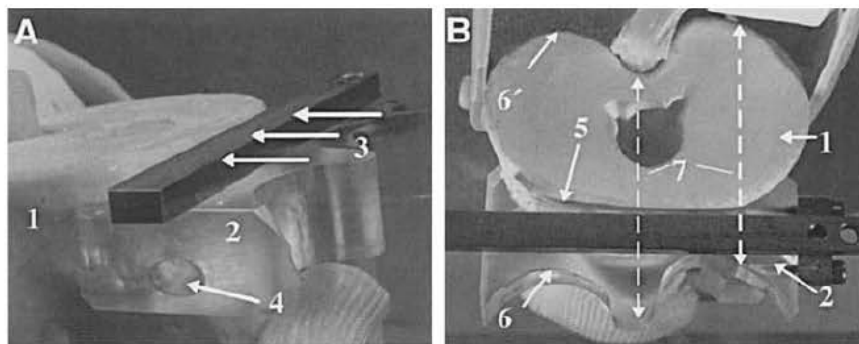


Fig 2A–B. Total knee arthroplasty: (A) laboratory investigation on a plastic bone model (1): individual template guiding the reference osteotomy (3) in tibial bone, optional fixation with a bone pin (4); (B) customized reference contact face (5) and copying profile (6) limiting cutting depth (7) to the dorsal contour (6) of tibial bone.

- Pages 31-32

- Figure 2 shows a feasibility study with a CT image based individual template for the reference tibial cut for total knee replacement on a plastic bone model.¹⁵ The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). In addition, topograms could be used to identify the bone axis. A conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone. The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes.

- Page 37

- One main drawback of the approach is that it depends on preoperative CT imaging. Moreover, no percutaneous applications are possible (except in dental or maxillofacial surgery). Lamellar contact faces (with ribs or arrays of pins) could be manufactured to compensate to a limited extent for remaining soft tissue.¹⁵ But as in most sensor based surface registration techniques, the accuracy and reliability of this technique depends on the accessibility and appropriate intraoperative identification of the rigid reference structures segmented and modeled in the preoperative image data.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher CAOS and many of the references identified in Defendants' Invalidity Contentions, including the Charted References, come from the same field of invention and disclose patient-specific guides for total knee arthroplasty. Furthermore, Radermacher taught that "[i]n total knee arthroplasty accurate placement of implant components with respect to the individual mechanical axis of the leg is essential," and the template taught in Radermacher CAOS aligned the tool guides based on the mechanical axis. Radermacher CAOS at 31-32 ("In total knee arthroplasty accurate placement of implant components with respect to the individual mechanical axis of the leg is essential. Conventionally, modular mechanical devices corresponding to the intrinsic shape of the implant components are used to guide the osteotomies and bores for the preparation of the implant's seat. By mounting these conventional tool guide systems on an individual template as a basic customized reference, it is possible to reproduce the preoperatively planned position exactly even in the case of severely deformed bone."). Thus, a POSITA would be motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants' Invalidity Contentions to include at least one guide that has a predetermined orientation relative to an anatomical or a biomechanical axis of the joint, at least under the construction implicit in Conformis' Preliminary Invalidity Contentions.

vii. PFC Sigma System (DPY_00009219 to DPY_00009477)

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 3

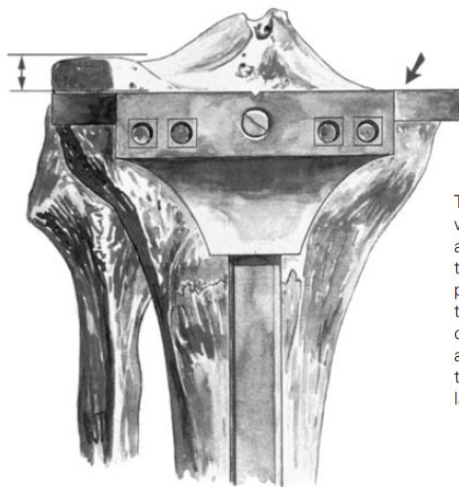
○

PREOPERATIVE PLANNING

Full-length extremity roentgenograms are obtained and the mechanical and anatomic axes identified. Where the intramedullary alignment system is selected, the angle of the two axes indicates the appropriate angle of the bushing to be used in conjunction with the intramedullary rod and the femoral locating device, thereby assuring that the distal femoral cut will be perpendicular to the mechanical axis. It is helpful to draw the femoral and tibial resection lines on the film as an intraoperative reference.

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 19

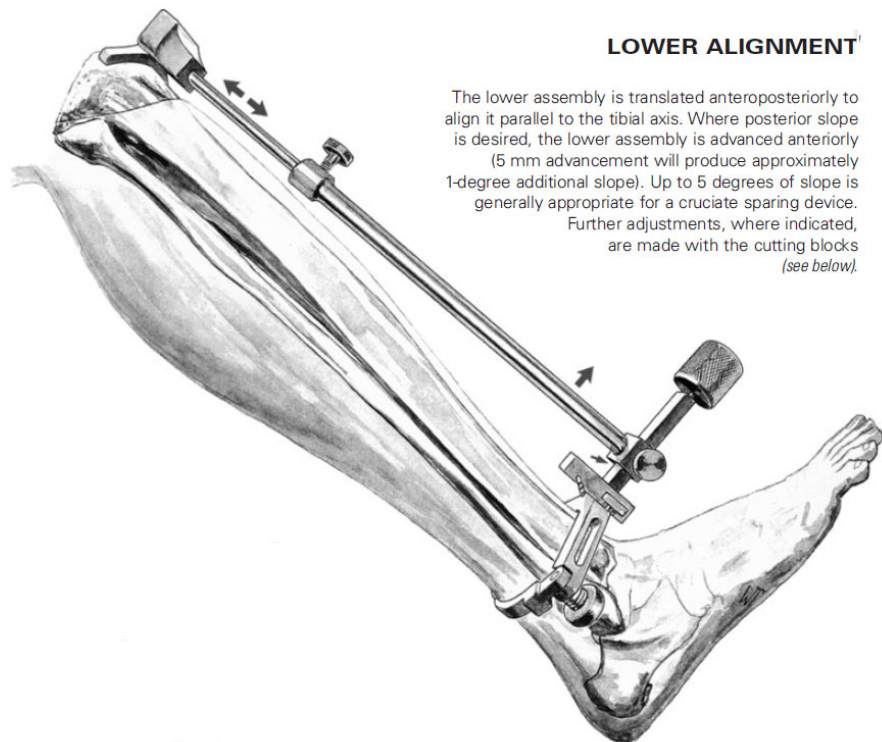
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The exact level of resection will vary according to patient anatomy. As the mediolateral transverse plane of the tibial plateau is usually 3 degrees from the perpendicular and the projected cut is perpendicular to the anatomic axis, more bone is typically removed from the lateral condyle.

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 21

○



- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 23

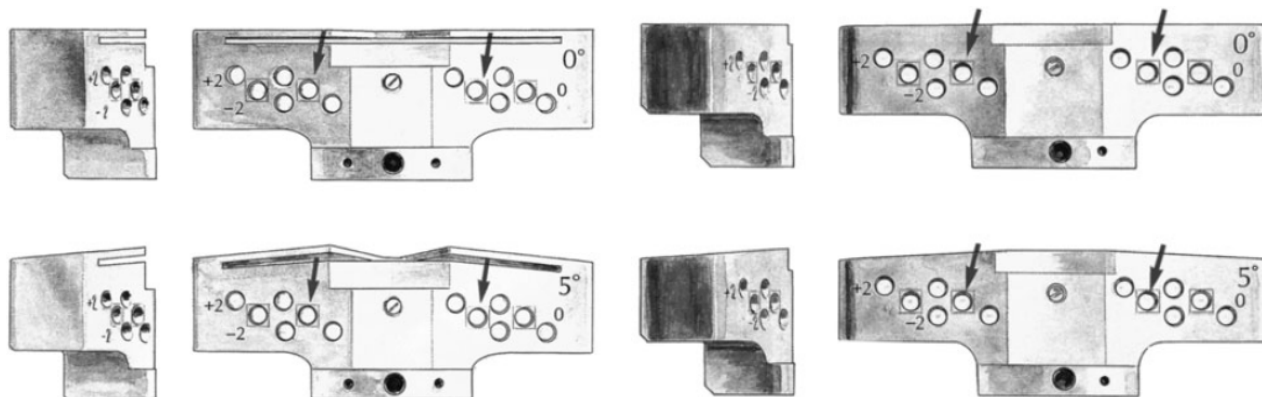
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THE TIBIAL CUTTING BLOCK

Cutting blocks are provided in surface or slotted versions and in 0 degrees and 5 degrees of posterior slope. One of the 0-degree blocks is selected initially. The holes are designated -2, 0 and +2, indicating in mm a greater or lesser amount of resected bone. The block is positioned onto the Steinmann pins using the 0 holes (the holes enclosed in □'s). The 5-degree block will give 5 degrees of additional posterior slope to that already established by the tibial alignment guide.

- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 23

○



A person of ordinary skill in the art would have been motivated to combine the teachings of the PFC Sigma System with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, PFC Sigma System and many of the references identified in Defendant's Invalidity Contentions, including the

Charted References, come from the same field of invention—instruments to perform total knee arthroplasty. Furthermore, the PFC Sigma System teaches that resections and the angles of resection in relation to a mechanical or anatomical axis can be determined preoperatively, and many of the Charted References teach determining the resections preoperatively. *See, e.g.*, PFC Sigma System at 7. Thus, to the extent not already disclosed, a POSITA would be motivated to include at least one guide that has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.

viii. Scuderi & Tria

- Page 177

- **PRINCIPALS OF INSTRUMENTATION**

- Tibiofemoral Alignment**

- The overall alignment of the knee must be in 5 to 10 degrees of anatomic valgus. The alignment is determined by the position of both the femoral and tibial components in the coronal plane of the joint. There are two basic schools of thought concerning the position of the knee joint.^{3,4} The most popular school references the mechanical axis of the lower leg. The tibial cut is made perpendicular to the tibial shaft and the femoral cut is made parallel to the mechanical axis of the femur (i.e., the line drawn from the femoral head through the middle of the tibia and through the middle of the ankle). The anatomic alignment references the mechanical axis of the lower leg but allows for the fact that the proximal tibial plateau is actually in a few degrees of varus. In this system the tibial cut is set anatomically (i.e., in 2 to 3 degrees of varus) and the femoral cut is made parallel to the mechanical axis with the addition of the 2 or 3 degrees. Hungerford and Krackow popularized this concept hoping to improve knee arthroplasty with greater anatomic precision (Fig. 24.1).

- Figure 24.1

○

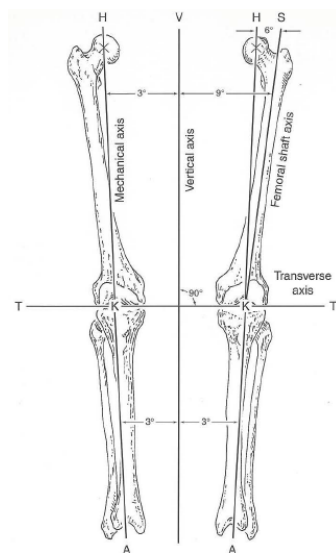


Figure 24.1. The figure on the left illustrates the mechanical axis of the knee. The figure on the right shows the femoral anatomic axis with the tibial reference line drawn to allow for the anatomic varus of the tibia of 3 degrees.

- Page 177

- **PRINCIPALS OF INSTRUMENTATION . . .**

The preceding discussion has only considered the angular relationship of the femur and the tibia in the coronal plane. The instruments must align each component in the sagittal, coronal, and horizontal planes.

- Page 179-180

- The tibial component must also be considered as a separate entity similar to the femoral component. Most tibial cuts are perpendicular to the tibial shaft in the coronal plane unless the knee system incorporates an anatomic 3 or 4 degrees of varus. In the sagittal plane the tibial cut is usually perpendicular or includes a slight posterior angulation to help with the flexion

range of motion improving the rollback of the femoral component on the tibial surface. Many knee systems include a slight posterior angulation in the polyethylene surface and cut the tibial plateau at a 90-degree angle. If the slope is built into the polyethylene, there must be some thinning of the polyethylene from the anterior to the posterior aspect of the surface. With the thinner inserts, it is possible to approach the critical thickness of 6 mm or less. Thus, some designs incorporate the slope in the tibial cut and then implant a polyethylene that is of uniform thickness from anterior to posterior and avoid the issue of changing polyethylene thickness.

- *See also* Pages 243-253.

A person of ordinary skill in the art would have been motivated to combine the teachings of the Scuderi & Tria with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Scuderi & Tria teaches surgical techniques for use in total knee arthroplasty. Furthermore, Scuderi & Tria teaches that "instruments [for total knee arthroplasty] must align each component in the sagittal, coronal, and horizontal planes," Scuderi & Tria at 177, and in the coronal plane there are a few known methods for aligning femoral and tibial cutting guides in relation to a biomechanical and/or anatomical axis. *See, e.g., id.* ("The most popular school references the mechanical axis of the lower leg. The tibial cut is made perpendicular to the tibial shaft and the femoral cut is made parallel to the mechanical axis of the femur (i.e., the line drawn from the femoral head through the middle of the tibia and through the middle of the ankle). The anatomic alignment references the mechanical axis of the lower leg but allows for the fact that the proximal tibial plateau is actually in a few degrees of varus. In this system the tibial cut is set anatomically (i.e., in 2 to 3 degrees of varus) and the femoral cut is made parallel to the mechanical axis with the addition of the 2 or 3 degrees."). Thus, to the extent not disclosed, a POSITA would be motivated to include at least one guide that has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.

ix. Insall

- Page 1577
 - **Alignment Guides**

It is generally agreed that restoration of the mechanical axis of the limb should be achieved. (As previously discussed, "restoration" may be an incorrect description for some individuals with habitual deviation from normal alignment.) Alignment is obtained by making appropriate cuts on the femur and tibia plus soft-tissue adjustments to provide the necessary stability (ligament balancing).

- Page 1578

- **Method of Alignment**

- Classic Method (Authors' Preferred Method)*

It is more convenient and thus our preference (Fig. 74.44) to initially create appropriate distal femoral valgus, but either the tibial or the femoral osteotomy may be performed first. We tend to vary the distal femoral valgus depending on the patient's body habitus. Varus knees are routinely cut in 7 degrees of valgus, whereas valgus knees are cut in 4 to 5 degrees of valgus. Nondeformed knees are cut at 6 to 7 degrees of valgus. In obese patients, we limit the amount of valgus to 5 degrees even when the patient presents with a varus deformity to avoid contact between the medial knee soft tissues. The tibial cut is made neutral to the tibial anatomic axis. Our desired alignment has essentially remained unchanged since Lotke and Ecker reported that distal femoral valgus of 4 to 6 degrees and a perpendicular proximal tibial cut resulted in the most favorable outcome.⁹⁴ Hsu et al⁶⁴ confirmed that 7 degrees of femoral valgus matched with 0 degrees of proximal tibial alignment resulted in the most even load distribution across a total condylar knee prosthesis.

- Anatomic Method*

In an attempt to recreate natural knee kinematics with a PCL retaining prosthesis, Hungerford used an anatomic method (Fig. 74.45) of lower limb alignment for TKA.⁶⁶ Femoral valgus is set at an anatomic 9 to 10 degrees, and the tibial cut is made in 2 to 3 degrees of varus, thereby creating an anatomic 6 to 7 degrees of lower extremity valgus. Hsu et al⁶⁴ demonstrated that these angles produce even load distribution across the knee joint in a cruciate retaining design. As noted above, if the surgeon is not experienced in this technique, intentional varus tibial cuts can easily result in accidental excessive tibial varus, creating uneven load distribution and ligament imbalance.

- Figures 74.44 & 74.45

○

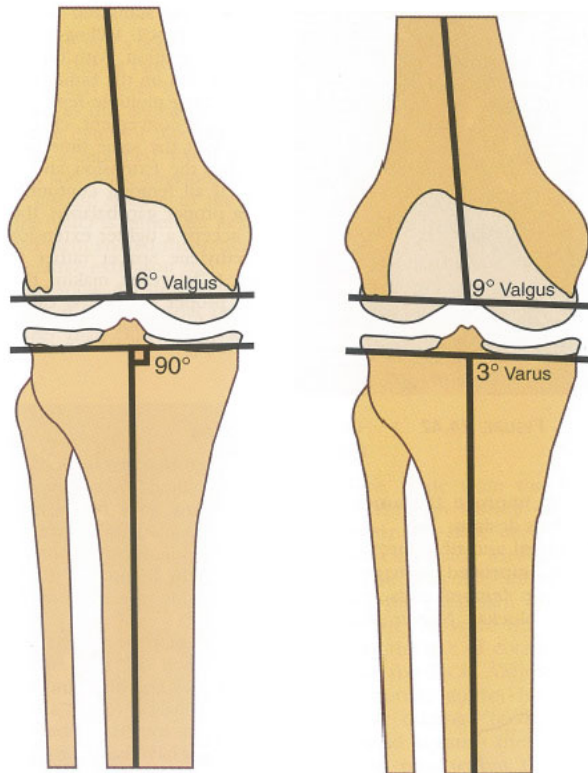


FIGURE 74.44 > Classic alignment. FIGURE 74.45 > Anatomic alignment.

A person of ordinary skill in the art would have been motivated to combine the teachings of Insall with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Insall teaches that in total knee arthroplasty "restoration of the mechanical axis of the limb should be achieved." Insall at 1577. Insall also teaches two methods of alignment related to a biomechanical or anatomical axis. *See, e.g.*, Pages 1578; Figs. 74.44 & 74.45.

Many of the references identified in Defendants’ Invalidity Contentions disclose devices for total knee arthroplasty. Thus, to the extent not disclosed, a POSITA would be motivated to include at least one guide that has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.

I. “Rotation Angle” Limitations

Position and/or orientation based on rotation angle, including as recited in the following Asserted Claims, was well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff’s infringement contentions:

Patent	Claim	Claim Language
129	1	wherein the guide defines a drilling path through at least a portion of the knee joint, the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.
161	1	wherein the articular repair system has a predetermined rotation angle and wherein the position and/or orientation [of the guide holes] is based on the predetermined rotation angle.
161	19	wherein the articular repair system has a predetermined rotation angle and wherein the position and/or orientation [of the guide holes] is based on the predetermined rotation angle.
304	1	wherein the articular repair system has a predetermined rotation angle and wherein the position [of the guide holes] is based on the predetermined rotation angle.
304	31	wherein the articular repair system has a predetermined rotation angle and wherein the position [of guide holes] is based on the predetermined rotation angle.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art
 - i. Asserted Patents

- '745 Patent, 4:38-40; '482 Patent, 4:47-50; '161 Patent, 4:45-48; '129 Patent, 4:6-9; '304 Patent, 4:6-9
 - U.S. Pat. No. 6,106,529 to Techiera issued Aug. 22, 2000 discloses an epicondylar axis referencing drill guide for use in resection to prepare a bone end for prosthetic joint replacement.
- '745 Patent, 69:11-15; '482 Patent, 69:19-23; '161 Patent, 69:20-24; '129 Patent, 43:65-44:2; '304 Patent, 44:3-7; '026 Patent, 52:59-63; '780 Patent, 6-10
 - Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee.
- '745 Patent, 97:57-61; '482 Patent, 98:1-5; '161 Patent, 98:1-5; '026 Patent, 80:65-81:2; '780 Patent, 81:10-14
 - For example, a standard surgical cut block as described for standard implants, for example in the knee the J&J PFC Sigma system, the Zimmer Nexgen system or the Stryker Duracon system, can be connected or placed on the mold.
 - ii. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018⁸
- Pages 9-12
 - Knee arthroplasty techniques have changed little since the introduction of intramedullary and extramedullary rods. Instead, improvements have been made to the orthopedic implants themselves. . . . Once the axes have been determined, the surgeon resects the damaged distal end of the femur and/or proximal end of the tibia to restore mechanical alignment to the joint. As Dr. Mayor explains, "[i]t is of the utmost importance that the distal femur and proximal tibia be cut perpendicular to the femoral and tibial mechanical axes, respectively." The distal femur and proximal tibia must also be cut at the appropriate depth to achieve proper joint spacing (e.g., not too tight and not too lax) while providing sufficient support for the implant. The femur and tibia are then farther resected so the exterior surfaces of the bones will match the interior surfaces of the implants, and so the implants will be rotationally aligned.
 - iii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

⁸ In the quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

- Paragraph 30
 - This cutting guide is placed on the flat surface of the distal femoral cut and is rotationally aligned (intraoperatively) by the surgeon relative to the epicondylar axis. The distal femur is then shaped such that the exterior surface of the distal femur matches the interior surface of the femoral implant. The femoral implant should be axially and rotationally aligned.
 - iv. Declaration of Dr. Thomas R. Oxland, *Conformis, Inc. v. Medacta USA, Inc.*, No. 19-1618-RGA (D. Del. Dec. 12, 2020)⁹
- Paragraph 63-64
 - In particular, Krackow describes “[t]he third technique involv[ing] specific referencing from the posterior femoral condyles or, alternatively, from any other fixed aspect of geometry.” Krackow, 125-126. Similarly, Krackow explains that “[a]n alternative reference may be found in the epicondylar axis. When used as a secondary reference it should be noted that this axis does not parallel the posterior condylar axis...” *Id.*, 129.

Likewise, articles in the field of joint arthroplasty in the 2001 to 2006 timeframe indicate that a POSITA would be familiar with referencing an anatomic landmark.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff’s infringement contentions. For example, the references charted in the Charted References taught positioning a drill/pin path based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants’ Invalidity Contentions. For example, the Charted References taught that proper alignment of a prosthesis, including proper internal/external rotation, can improve the function and increase the longevity of the resulting prosthesis. Furthermore, many of the Charted References are from the same field of invention, tools for joint arthroplasty.

⁹ Krackow in the quotation below refers to THE TECHNIQUE OF TOTAL KNEE ARTHROPLASTY by Kenneth A. Krackow.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Techiera

- Abstract

- The tool includes adjustable assemblies coupled to a main body for determining a preparatory cut to fit a prosthesis, for example by drilling positioning holes or otherwise setting one or more preparatory cuts, and further includes elements for sizing the prosthesis. The body carries a sighting, pointer or caliper assembly which aligns to or is positioned on the medial and lateral epicondyles, and aligns the body along the epicondylar axis, while one or more other assemblies determine a line, depth or other positioning component to adjust the position of the body with respect to other landmarks before anchoring the assembly and performing cuts. In prototype embodiments, the body positions a drill guide to locate positioning pin holes in the femur.

- Column 1, Lines 18-21

- The present invention relates to tools and jigs for laying out machine cuts to prepare a bone for receiving a correctly sized and aligned prosthetic component, such as a component of a prosthetic knee joint assembly.

- Column 1, Lines 39 -63

- The bone cuts made to effect the placement and orientation of the femoral component of the prosthesis determine and form the joint gaps in extension and flexion. The size and shape of these two gaps affect final bone orientation as well as joint tensioning and clearances. The femur must be so oriented, with respect to the cut surfaces defining the prosthesis fit, so as to satisfy numerous constraints. With respect to their effect on final orientation, the flexion gap is related to internal/external orientation of the femur, while the extension gap is related to the varus/valgus orientation of the femur.

Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur, while in flexion the joint gap is such as to place the femoral component in either neutral or external rotation to assure proper patellar tracking with the femoral component. Furthermore to fit the femoral component, the gaps created by the bone

resections in both flexion and extension should be rectangular. In flexion, the relevant natural articulation surface corresponds to the tangent plane of the posterior epicondyles, and in extension, to that of the distal epicondylar surface. However, by performing A/P cuts by reference to the posterior surfaces, there is some risk of notching the anterior cortex. Thus, many surgeons set the A/P cut positions with reference to the anterior cortex.

- Column 2, Lines 14-19

- In general, the surgeon may have to exercise judgment as the various cuts are made. Also the Steps in reaching a determination will vary depending upon the initial landmarks used for setting preliminary resections, both as a matter of the surgeon's preferred procedure and as constrained by any patient specific features or disease.

- Column 2, Lines 20-46

- Recently, some interest has arisen in using the epicondylar axis as a guide line, either by marking its position as a reference for confirming alignment or making slight adjustments during fitting, or as a primary landmark when disease or a previous arthroplasty have altered or obliterated the usual primary landmarks. When used to set internal/external rotation this provides improved balance of the collateral ligament tension between flexion and full extension. However, it can be awkward to determine the epicondylar axis, and while the clinical epicondylar prominence may be considered in advance of surgery, this feature varies somewhat from a true geometric center of the articulation axis. Thus, when used as a reference, the epicondylar axis is generally marked on the distal femoral cut surface, when the leg is in flexion, viewing the exposed epicondyles head-on. Thereafter, the surgeon may use the marked line to harmonize or check the preparatory cuts or axes determined by other measurement jigs and empirical offsets, such as to adjust an axis original set parallel to the posterior epicondylar tangent plane, or a fitting referenced to the trochlear groove. The resulting sequence of steps may be complex and time consuming.

Accordingly, it would be desirable to provide a tool to simplify procedures during surgery for performing preparatory bone cuts or setting alignment marks to prepare the bone to receive a prosthetic joint component aligned with respect to the epicondylar axis.

- Column 2, Line 56-Column 3, Line 5

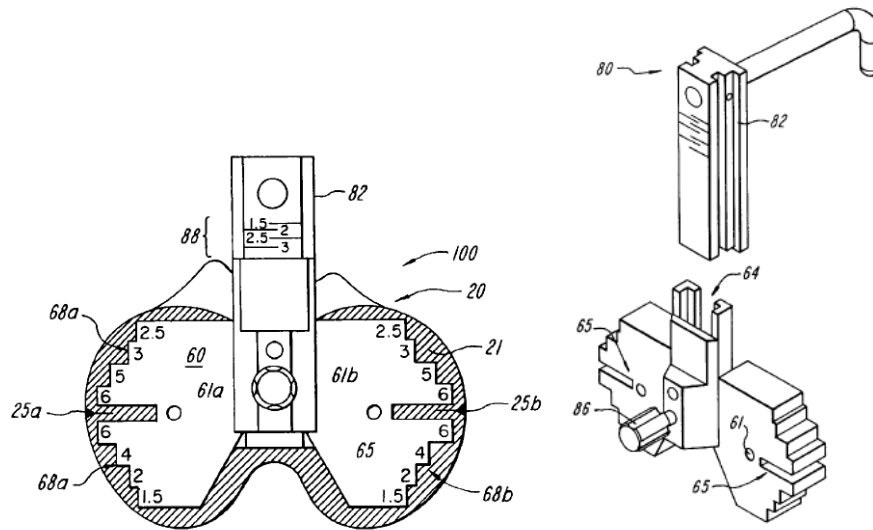
- The tool is used at the distal femoral resected surface, and includes one or more assemblies coupled to a main body for alignment with the epicondylar axis, and which set the orientation of the main body. The main body positions a cutter, e.g.,

includes a drill guide or saw blade guide. One or more further units may couple to the body for Sizing a prosthetic component, or fixing its position, for example by locating A/P positioning holes or otherwise more fully determining or setting one or more preparatory cuts. The epicondylar alignment assemblies may include an epicondyle sighting assembly or a pointer, and the additional units may include an A/P setting jig, Such as a cortex hook assembly which is mounted in such a way as to enable forced lateral translation to accommodate an asymmetry or deformity of the bone end. One or more components of the tool may slide in the central body to facilitate alignment on the bone end,

- Column 3, Lines 46-61
 - As shown in FIG. 1, a first prototype tool 100 is intended for use during surgery, and has a body which lies across the distal resected end 21 of a femur 20, which may be either the right or left femur. By way of overview, the tool is preferably used once the surgeon has made the distal femoral cut, and includes a central body 60 which includes a drill guide 61, and which is positioned across the distal bone end by an axis- or line-referencing assembly, discussed more fully below. In this embodiment the line-referencing assembly is implemented by a simple pair of viewing apertures or slots 65 in the body 60. As illustrated, the body 60 has been placed by the surgeon so that the apertures 65 are directly over a line or pair of marks 25a, 25b which are previously scribed by the surgeon to mark the projection of the epicondylar axis on the distal bone surface. So positioned, the body 60 places the drill guide holes 61 on the axis.

- Figures 1 & 2

-



- Column 4, Lines 17-23

- The slidable carriage of the drill positioning guide 60 on the post 82 of which the A/P position is set, allows the positioning pin holes for a prosthesis and/or preparatory cutting blocks to be laid out and drilled on the bone end in the correct A/P offset while the body 60 is simultaneously oriented by the epicondylar axis sighting assembly 65 in alignment along the epicondylar axis.

- Column 5, Lines 37-40

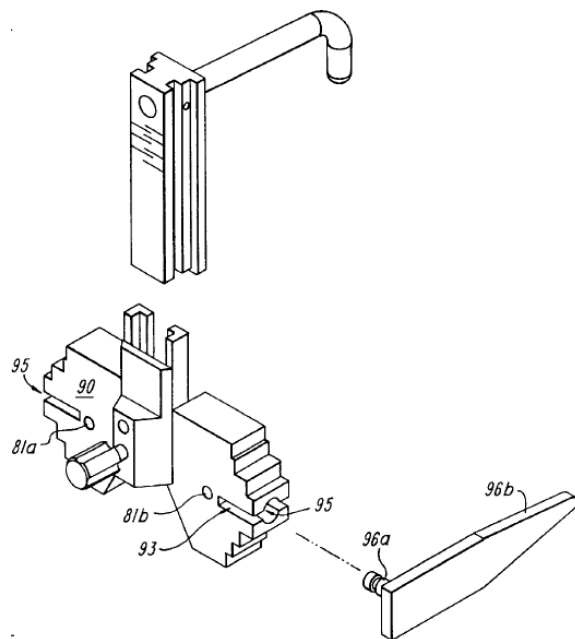
- It should be noted that the drill guide holes 61a, 61b illustrated in FIG. 1 correspond to a pair of positioning pins having a fixed spacing as used for example by one prosthesis manufacturer in all sizes of a line of femoral components.

- Column 6, Lines 10-18

- As shown in FIG. 5A, the central body 90 of the component may be formed as a unit which, rather than being aligned by sighting slots 65 (FIG. 1), is provided with medial and lateral positioning bores 95, each of which accommodates a pointer arm 96 that may be moved in and out along the axis of the bore on a mounting shaft 96a so that the tip of the arm 96b is aligned with the prominence of the corresponding epicondyle. The two arms 96 thus position the body 90 parallel to the epicondylar axis.

- Figure 5A

○



- Column 6, Lines 46-50
 - When the proper fit is achieved, holes are drilled into the distal resected femur using the drill positioning guide holes 81a, 81b. The device is then removed, and the surgical procedure continues using standard A/P cutting blocks pinned in the two drill holes so made.
- Column 6, Line 64-Column 7, Line 7
 - Among the advantages of the structure of the device, rather than eyeballing or simply marking an axis to use as a confirmatory check or secondary adjustment data, the present invention advantageously provides a direct and positive positioning for a standard set of cutting blocks to achieve a fit compatible with the natural articulation geometry and to adjust that fit for proper patellar tracking. This results in a flexible preparation procedure, and permits several practical adjustments to be carried out with enhanced control or perception of the tensioning and positioning of necessary components.

A person of ordinary skill in the art would have been motivated to combine the teachings of Techiera with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Techiera teaches to balance joint extension and flexion and how bone cuts should be made to balance joint extension and flexion and place a prosthesis in proper rotational alignment. *See, e.g.*, Techiera at 1:39-49 ("The bone cuts made to effect the placement and orientation of the femoral component of the prosthesis determine and form the joint gaps in extension and flexion. The size and shape of these two gaps affect final bone orientation as well as joint tensioning and clearances. The femur must be so oriented, with respect to the cut surfaces defining the prosthesis fit, so as to satisfy numerous constraints. With respect to their effect on final orientation, the flexion gap is related to internal/external orientation of the femur, while the extension gap is related to the varus/valgus orientation of the femur."). Techiera teaches proper internal/external rotation of a prostheses is important for patellar tracking and better outcomes. *See, e.g., id.* at Abstract ("The drill holes [in the guide] may set a position for a standard cutting block to fit a femoral end component. Further, by manually shifting the assembly while the cortex hook contacts the anterior femoral surface, the prosthesis may be aligned with the trochlear groove of the femur to improve patellar tracking. Preferably, the tool places drill holes in position for a standard set of cutting blocks to fit a femoral end component of a prosthetic knee."); *id.* at 1:50-54 ("Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur, while in flexion the joint gap is such as to place the femoral component in either neutral or external rotation to assure proper patellar tracking with the femoral component."); *id.* at 2:20-27 ("Recently, some interest has arisen in using the epicondylar axis as a guide line, either by marking its position as a reference for confirming alignment or making slight adjustments during fitting, or as a primary landmark when disease or a previous arthroplasty have altered or obliterated the usual primary landmarks. When used to set internal/external rotation this provides improved balance of the collateral ligament tension between flexion

and full extension.”). A POSITA also would recognize that applying the teachings in Techiera could reduce the complexity and time of total knee arthroplasty surgery. *See, e.g.*, Techiera at 1:50-54 (“Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur, while in flexion the joint gap is such as to place the femoral component in either neutral or external rotation to assure proper patellar tracking with the femoral component.”); 2:32-46 (“Thus, when used as a reference, the epicondylar axis is generally marked on the distal femoral cut surface, when the leg is in flexion, viewing the exposed epicondyles head-on. Thereafter, the surgeon may use the marked line to harmonize or check the preparatory cuts or axes determined by other measurement jigs and empirical offsets, such as to adjust an axis original set parallel to the posterior epicondylar tangent plane, or a fitting referenced to the trochlear groove. The resulting sequence of steps may be complex and time consuming. [¶] Accordingly, it would be desirable to provide a tool to simplify procedures during surgery for performing preparatory bone cuts or setting alignment marks to prepare the bone to receive a prosthetic joint component aligned with respect to the epicondylar axis.”). Finally, a POSITA would be motivated to combine the teachings of Techiera with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References, as Techiera comes from the same field of invention as many of the identified references—joint arthroplasty, particularly, total knee arthroplasty. Thus, to the extent not already disclosed, a POSITA would have been motivated to position or orient drill paths in a template based on a predetermined rotation angle of a prosthesis.

ii. Arima

- Page 1331-32
 - Rotational alignment of the femoral component in total knee arthroplasty affects varus-valgus stability during flexion as well as the position of the patellar groove. When viewing the distal aspects of the femoral condyles in a knee with normal osseous anatomy, external rotation of the femoral component relative to a line connecting the posterior aspects of the femoral condyles places the component in the correct rotational position relative to the upper surface of the tibia when resection of the tibial surface is perpendicular to the long axis of the tibia. This rotational position also places the patellar groove in a favorable position anteriorly, moving it slightly laterally so that the patella can track in a normal position in the extended knee and avoid the increased Q angle created by an internally rotated femoral component. However, a valgus knee has severely distorted distal femoral architecture. The lateral femoral condyle is abnormally small anteriorly, distally, and posteriorly, making it especially difficult to determine correct rotational alignment. While the posterior aspects of the femoral condyles serve as reliable landmarks for rotational alignment of a normal knee, in a valgus knee they produce a transverse reference axis that is internally malrotated. Other landmarks have been suggested to guide the surgeon in rotational alignment of the femoral component. The transepicondylar axis can be used, but it is difficult to localize the peaks of the epicondyles precisely. Location of the epicondyles is even more difficult during the operation because they are

obscured by the patella, overlying ligaments, and adipose tissue. The intercondylar notch and patellar groove, however, are clearly visible and accessible during total knee arthroplasty. Use of these anatomical landmarks to define an anteroposterior axis to assist in rotational alignment of the femoral component in unicompartmental knee replacement has been described and is currently a successful clinical technique.

- Figures 1 & 3

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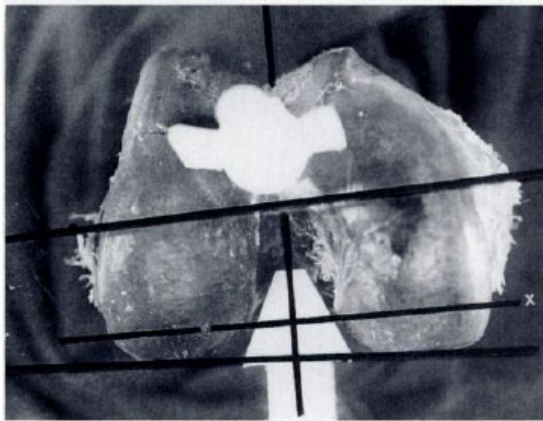


FIG. 1

Photograph of a cadaveric knee specimen with the Plexiglas plate and axes. A line (x) drawn perpendicular to the anteroposterior axis lies at an angle of 4 degrees of external rotation relative to the posterior condylar axis. The epicondylar axis in this specimen lies at an angle of approximately 8 degrees of external rotation relative to the posterior condylar axis.

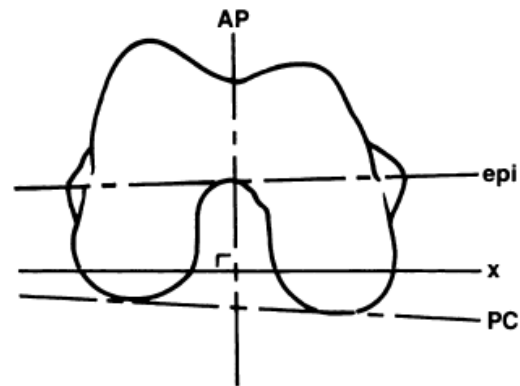


FIG. 3

Diagram of the alignment axes in a knee with a normal condylar shape. Resection perpendicular to the anteroposterior axis (AP) or parallel to the epicondylar axis (epi) results in a resection line (x) that is slightly externally rotated relative to the posterior condylar axis (PC). This results in correct positioning of the femoral component.

- Figure 4

-

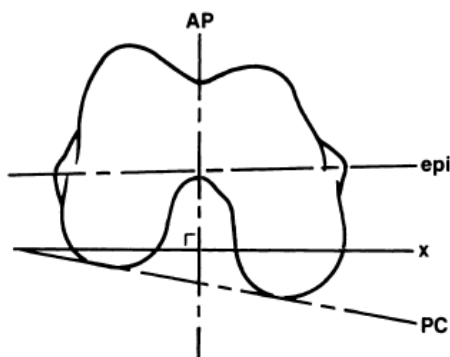


FIG. 4

Diagram of the alignment axes in a knee with severe valgus deformity and a shortened lateral femoral condyle. Resection perpendicular to the anteroposterior axis (AP) or parallel to the epicondylar axis (epi) results in a resection line (x) that is extremely externally rotated relative to the posterior condylar axis (PC). This results in underresection of the lateral femoral condyle but in correct rotational alignment of the femoral component relative to the other structures, including the patellar groove. Resection parallel to the posterior condylar axis results in severe internal rotational malposition of the femoral component.

- Page 1333-34

- Our data confirm the results of studies by Berger et al. and by Yoshioka et al., which showed the epicondyles to be reliable anatomical landmarks. We found that radiographic measurements of the epicondylar positions relative to the posterior condylar surfaces produced a transepicondylar axis that was almost as accurate as the anteroposterior axis. . . . Use of the anteroposterior axis for rotational alignment was more reliable and resulted in a range of -1.0 to 10.0 degrees.

- Page 1334

- In a knee with a normal condylar shape, it can be predicted that resection of the femoral condyles parallel to or in slight external rotation relative to the posterior condylar axis will result in correct rotational alignment of the implant relative to the other landmarks. However, in a valgus knee, . . . resection relative to the epicondyles or relative to a perpendicular to

the anteroposterior axis results in minimum resection of a lateral femoral condyle: the femoral resection surfaces may be as being in extreme external rotation (Fig. 4). Conversely, if equal amounts are resected from the posterior aspects of the femoral condyles in a severely valgus knee, one would expect malposition of the femoral component in excess internal rotation leading to medialization of the patellar groove in the extended position (Fig. 5). The anteroposterior-axis method appears to be more reliable and is certainly easier to use than the transepicondylar-axis method. However, when there is severe anterior and posterior destruction of bone, as is found in revision total knee replacement, the transepicondylar axis may be the only reliable landmark for rotational alignment.

A person of ordinary skill in the art would have been motivated to combine the teachings of Arima with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that applying the teachings in Arima and setting a predetermined rotation angle based on an anatomical landmark or axis can result in better function of the replaced knee. *See, e.g.*, Arima at 1331 ("Rotational alignment of the femoral component in total knee arthroplasty affects varus-valgus stability during flexion as well as the position of the patellar groove. When viewing the distal aspects of the femoral condyles in a knee with normal osseous anatomy, external rotation of the femoral component relative to a line connecting the posterior aspects of the femoral condyles places the component in the correct rotational position relative to the upper surface of the tibia when resection of the tibial surface is perpendicular to the long axis of the tibia."); 1334 (explaining the importance of the right amount of resection so as to obtain the correct rotational position of the implant). Further, a POSITA would appreciate that using the anteroposterior axis to set rotation angle can be advantageous when deformity of the knee obscures other anatomical landmarks, which can be the case in many knees undergoing total knee arthroplasty. *See, e.g.*, Arima at 1334 ("Use of the anteroposterior axis for rotational alignment was more reliable and resulted in a range of -1.0 to 10.0 degrees. A variation of this method has been used for rotational alignment of the femoral component in medial unicompartmental arthroplasty³. In many patients who have osteoarthritis with varus deformity, the posteromedial articular cartilage has been destroyed and the posterior surfaces are not reliable landmarks for rotational alignment. However, a rod aligned with the deepest part of the patellar groove and the center of the intercondylar notch consistently restored proper rotational alignment in a series of cadaveric femora that had a unicompartmental arthroplasty³. The same principle applies to the valgus knee. Often, the lateral posterior femoral deformity is extreme in such a knee, and other anatomical landmarks must be used as guides for the rotational position of the femoral component."). Finally, a POSITA would be motivated to combine the teachings of Arima with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References, as Arima comes from the same field of invention as many of the identified references—joint arthroplasty, particularly, total knee arthroplasty. Thus, to the extent not already disclosed, a POSITA would have been motivated to position a prosthesis, and thus the drill hole(s) for the stem(s) of the prosthesis, based on a predetermined rotation angle of the prosthesis.

Of note, in IPR2017-00510, the Board invalidated, *inter alia*, claims 18 and 50 of U.S. 7,981,158 that recite the additional steps of “determining a rotational position of an implant and wherein the guide is aligned based at least in part on the determined rotational position of the implant” in light of Radermacher’s CAOS article, Woolson, Alexander and Arima. *See* IPR2017-00510, Paper 42 at 52-53.¹⁰ Arima was specifically cited for these limitations. *Id.* at 53. Conformis did not dispute that Arima disclosed the relevant limitations. The Board opined:

We are persuaded by Petitioner’s contentions. Arima discloses that the anteroposterior axis is reliable landmark for rotational alignment in a valgus knee, the posterior aspects of the femoral condyles are reliable landmarks for rotational alignment in a normal knee, and a transepicondylar axis may be used as a (less reliable) landmark for rotational alignment in the knee. *See* Ex. 1085, 1331. Additionally, Arima’s Figure 3 depicts resection relative to anteroposterior, epicondylar, and posterior condylar axes. *Id.* at 1332. Accordingly, we are persuaded that a person of ordinary skill in the art would have been motivated to use any of these axes in determining an appropriate rotational position of the implant because this would be a simple substitution of one known reference axis for another, to obtain the predictable result of properly reconstructing the implant within the knee joint. *See* Ex. 1002 ¶¶ 180, 186, 190.

IPR2017-00510, Paper 42 at 53-54.

iii. Krackow

- Page 96

- **Sagittal Plane Orientation**

¹⁰ *E.g.*, ’158 Patent, Claim 1 (“1. A method of generating a patient-matched surgical tool, the method comprising: obtaining first image data associated with at least a portion of a joint of a patient; obtaining second image data associated with at least a portion of the joint; deriving an electronic model of at least a portion of the joint using at least the first image data; creating a surgical tool using, at least in part, the electronic model; wherein the tool includes a contact surface substantially matched to a corresponding surface of the joint and a guide for directing movement of a surgical instrument; and wherein the position or orientation of the guide relative to contact surface is adapted at least in part based on information derived from the second image data.”); Claim 18 (“The method of claim 1, further comprising determining *a rotational position of an implant* and *wherein the guide is aligned based at least in part on the determined rotational position of the implant.*”).

The issue of proper joint line orientation in the sagittal plane will be discussed briefly. In the classical sense, the cut was made perpendicular to the tibial shaft axis viewed from the side. More recently, instrumentation systems and surgical techniques, independent of instrumentation systems, have sometimes sought the creation of a posteriorly sloping joint line, ranging from a 2- or 3-degree slope to as much as a 10-degree or more posterior slope. This slant should not, in itself, alter the varus-valgus angulation in the frontal plane, which is our main consideration in this section. Arguments for and against performing a posteriorly sloping cut range from preservation of best subchondral bone to concerns over the presence of a sloped joint in the absence of an anterior cruciate ligament.

- Page 125
 - To date three approaches have been concerned with establishment of rotation of the femoral component. Under consideration here are external rotation and internal rotation, i.e., rotation about a longitudinal axis, (e.g., the shaft or the mechanical axis from the hip). The first of these is the condition of simply aligning a cutting instrument with the room or the “horizon.” This was probably the most common approach in the early years of total knee arthroplasty. The second is the attempt to orient the anterior and posterior femoral cuts in a rotational sense so that the flexion space created is approximately rectangular. The third technique involves specific referencing from the posterior femoral condyles or, alternatively, from any other fixed aspect of femoral geometry.

- Figure 5-5

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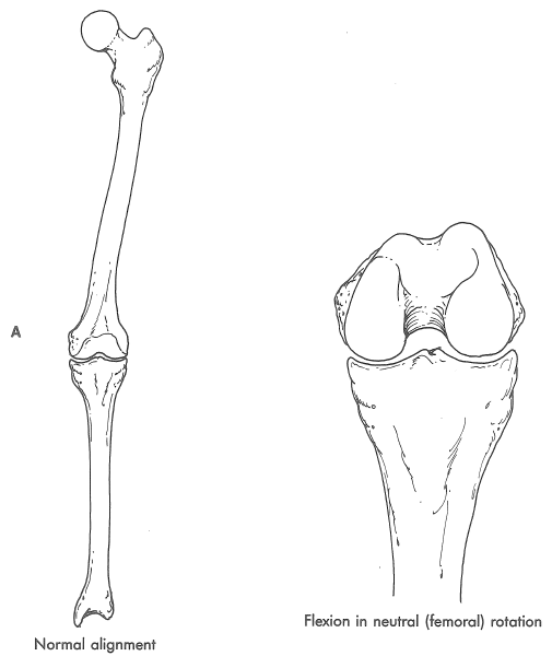


FIGURE 5-5

A, Outline of femur and tibia in extension and flexion. Essentially normal orientation of joint line is seen in both projections.

- Page 128

- Especially in these cases, if the surgeon places a femoral component into a position of normal, anatomic rotational alignment, it will be necessary to key off or align from specific bony landmarks.

- Page 129

- Because the goal is commonly to reestablish alignment of the femoral condyles, referencing from the femoral condyles themselves seems to be reasonable to the extent that they are not grossly misshapen. An alternative reference may be found in the epicondylar axis. When used as a secondary reference it should be noted that this axis does not parallel the posterior condylar axis but is approximately 5 to 10 degrees externally rotated from it (Figure 5-6).

- Figure 5-6

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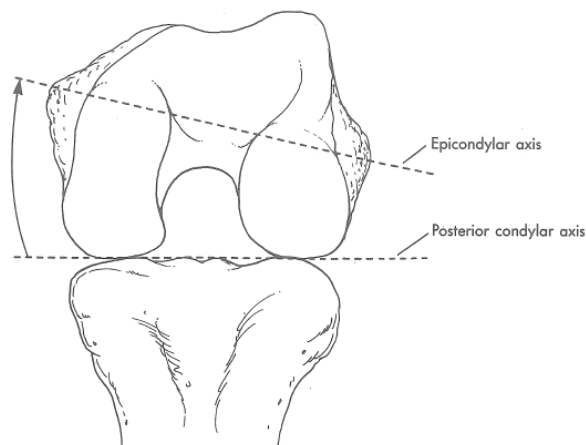


FIGURE 5-6

End-on view of femur and proximal aspect of tibia. Line drawn across posterior femoral condyles can be used to define posterior femoral condylar axis. Another line drawn connecting centers of medial and lateral epicondyles can be termed *epicondylar axis*. Both may be considered bony landmarks for rotational alignment. However, in a normal distal femur these axes are not parallel. Interepicondylar axis typically has a relatively externally rotated attitude with respect to posterior femoral condylar axis. Lateral epicondyle is closer to joint line than medial one in flexion and extension.

- Page 136-137

- So far, the discussion has covered how to assess joint rotation and how instrumentation aids the surgeon in placing the components properly in this regard. The consequences of abnormal rotational changes in component position should also

be considered. These clearly relate to ligamentous attachment points and may or may not relate to flexion-extension ligament stability and to issues of patellofemoral stability (Figure 5-11).

Femoral Side

On the femoral side, external rotation of the femoral component is diagramed in Figure 5-11, *B*. It leads to changes in both the medial and lateral collateral origins relative to the joint surfaces such that the medial collateral ligament would be proportionately posterior as the lateral collateral was moved anterior. Internal rotation of the femoral component would lead to the opposite, namely, a posteriorly posed lateral collateral ligament and anteriorly positioned medial collateral ligament (Figure 5-11, *C*). The anteriorly positioned ligaments would be expected to lead to tightness in flexion and corresponding laxity in extension, whereas the posteriorly positioned collateral side should be taut in extension and relatively lax in flexion.

It is also important to note that the tracking pattern of the components would be “forced,” at least in flexion. In full extension, or toward full extension, in a knee design that does not involve a close constraint or confirmational matching of the femoral and tibial components, a few degrees of femoral component internal or external rotation would not be expected to lead to any difference in position between the femoral bone, tibial component, and tibial bone; hence no sensation of difference in ligament stability owing to the rotational play, which is being assumed. However, as the tibia and the tibial component move into relative flexion and track against the posterior femoral condyles (assuming the tibia is to articulate on the femoral condyles), the abnormally rotated position of the femoral bone with respect to the femoral condyles is forced to equate to an abnormally rotated position with respect to the tibial component and tibia. Alterations in ligament and capsular tension are not theoretical, but real.

- Figure 5-11

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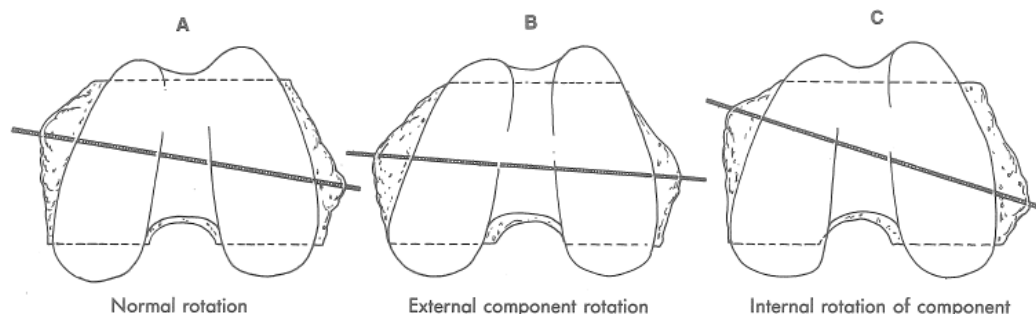


FIGURE 5-11

Influence of femoral component (anterior and posterior femoral cut) rotation on relative position of epicondylar axis. **A**, Anatomically positioned pair of anterior and posterior femoral cuts performed and component in place. Epicondylar axis has normal relationship to new posterior prosthetic condylar axis. **B**, Prosthetic femoral component externally rotated with respect to end of femur. Interepicondylar axis has different orientation with respect to posterior femoral condyles. Here epicondylar axis is oriented somewhat downward on medial side. With this arrangement, trochlear groove of femoral component would tend to be more lateral and patella would tend to track more medially. **C**, Internally rotated anterior and posterior femoral cuts and correspondingly internally rotated prosthetic femoral component. Epicondylar axis has relative, externally rotated orientation when compared to axis of posterior femoral condyles. Trochlear groove sits relatively medial with respect to patella, which tends to move off laterally.

- Page 134

- Although the femoral condyles can indicate femoral rotation, no such welldefined axis exists for the tibia. Several possibilities are present. The following consistencies and limitations should be appreciated:
 1. The overall appearance of the proximal joint surface of the tibia can be considered. In particular, a midtransverse axis and/or a posterior cortical axis can be established. Bone loss, osteophyte formation, and general anatomic variability must be taken into account (Figure 5-9). Furthermore, the normal configuration of the posterior cortex extending further posteriorly on the medial than on the lateral side should be noted.

2. The next readily available anatomic structure is the patellar-tibial tuberosity, which typically lies lateral to an anterior midline. Generally, it would be inappropriate to aim a tibial plateau so that its neutral rotation axis points straight to the tibial tubercle (Figure 5-9).
3. Another anatomic landmark is the intermalleolar axis.
4. Still another landmark is the overall “long axis” of the foot as it is held up into neutral position of plantar flexion/dorsiflexion (Figure 5-10). Both of these last two points the intermalleolar axis and the “long axis” of the foot are moderately variable—as much as 15 to 20 degrees in a significant number of people. Because of these aspects of anatomic and rotational variability, it is wise to assess clinically these landmarks preoperatively. One needs to know the starting point.
5. A final consideration for referencing tibial rotation might be the position established by the soft tissues. This technique involves acceptance of the tibial rotation defined by the soft tissue attachments. By this method, preparation of some or most of the joint surfaces has been performed, after which rotation of the tibia with regard to the femur is guided by soft tissues. The neutral position of the tibia is marked to parallel that of the femur in extension when longitudinal tension is applied across the joint. The rotation position of the tibia is taken to be the natural resting position, which is achieved during this tension-stress testing.

- Figure 5-9

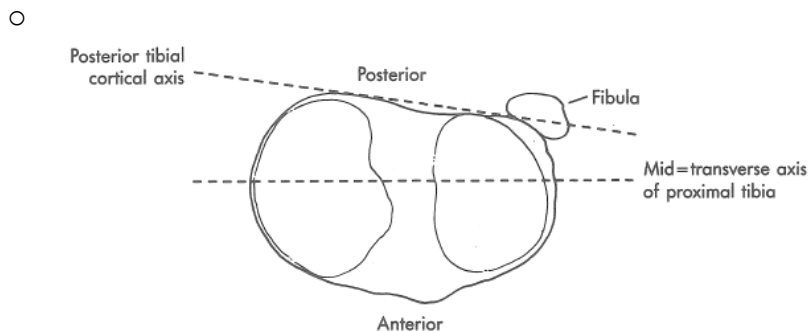


FIGURE 5-9

Upper aspect of tibia viewed from above promotes understanding normal bony geometry as it relates to rotational attitude of the tibia. Construct axis along posterior cortices, that is, respective medial and lateral prominences of tibia. Imagine midtransverse axis to locate position of tibial tubercle. Note in normal situation posterior tibial cortex extends farther posteriorly in medial aspect than lateral aspect. Midtransverse axis may be difficult to define. Normal tibial tubercle appears to be relatively lateral and not in center midline.

- Page 137

- On the tibial side, rotational alteration of the tibial component—assuming normal position of the collaterals to begin with—would also lead to corresponding anterior and respective posterior displacement of ligament attachments relative to the tibial component surface geometry. This would be expected to lead to general “tightening” for a given prosthetic thickness, which would persist throughout range of motion. If significant rotational freedom exists, there may, in fact, be no alteration of actual relationship between the femur, femoral component, and tibial bone, because the tibial component, not the tibial bone, assumes the different rotation. With close confirmational match between femoral and tibial components and with components inserted at a state of ligament “tightness,” either the rotational attitude is maintained by the roller and trough, or the components sublux.

A person of ordinary skill in the art would have been motivated to combine the teachings of Krackow with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. Krackow teaches the effects of rotation angles of implant components on laxity in extension and flexion. *See, e.g.*, Krackow at 136-137 (“On the femoral side, external rotation of the femoral component is diagramed in Figure 5-11, *B*. It leads to changes in both the medial

and lateral collateral origins relative to the joint surfaces such that the medial collateral ligament would be proportionately posterior as the lateral collateral was moved anterior. Internal rotation of the femoral component would lead to the opposite, namely, a posteriorly posed lateral collateral ligament and anteriorly positioned medial collateral ligament (Figure 5-11, C). The anteriorly positioned ligaments would be expected to lead to tightness in flexion and corresponding laxity in extension, whereas the posteriorly positioned collateral side should be taut in extension and relatively lax in flexion.”). Krackow also teaches that “if the surgeon places a femoral component into a position of normal, anatomic rotational alignment, it will be necessary to key off or align from specific bony landmarks.” Krackow at 128. Thus, a POSITA would be motivated to apply Krackow’s teaching in pre-operative and intraoperative planning as well as surgical guide design, and position a tool guide with reference to the desired/predetermined implant rotation angle so that the final implant can be properly placed/oriented.

iv. Jazrawi et al.

- Abstract

- The preoperative assessment of implant rotational alignment is critical in planning treatment because the femoral or tibial component (or both) may need to be revised if malpositioned. The purpose of this study was to ascertain the accuracy of computed tomography (CT) scan for determining rotational alignment of femoral and tibial components in TKA.

- Page 761

- Patellofemoral complications (eg, patella subluxation or dislocation, patellar clunk, wear or loosening of the patellar component, and patella fracture) are the most common complications after total knee arthroplasty (TKA), occurring in 30% of cases [1,2]. Poor patella tracking or dislocation can be the result of malrotation of the tibial or femoral components (or both),Malrotation also causes rotational incongruity between femoral and tibial components, resulting in increased contact stresses along the tibia during flexion [3].

- Page 762

- Femoral component rotation was measured as the angle formed between a 0.062-mm Kirschner wire (K-wire) placed in the epicondylar axis of the femur, as described by Berger et al [4] and a second K-wire secured to the top of the inner pegs of the femoral component with polymethyl methacrylate to mark its geometric center (Fig. 1). Tibial component rotation was determined from the angle formed between a K-wire fixed with polymethyl methacrylate to the posterior aspect of the tibial

component and a second K-wire (secured with stainless steel tacks) 2 cm below the joint line along the posterior condyles of the tibial specimens (Fig. 2).

- Figure 1

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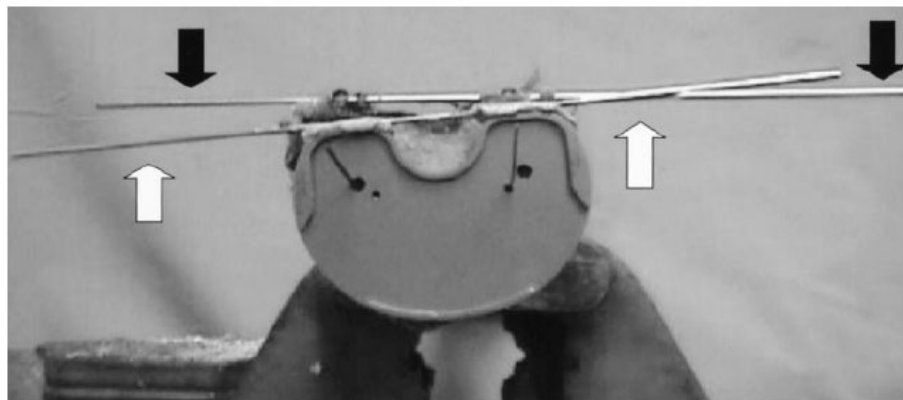
Fig. 1. Digital image of externally rotated femoral component. Black arrows mark the epicondylar axis; white arrows mark femoral pegs.



- Figure 2

-

Fig. 2. Digital image of internally rotated tibial component. Black arrows mark the posterior tibial axis; white arrows mark the posterior aspect of the tibial component.



- Page 764

- Alignment has been implicated as a primary or contributing cause of many complications in TKA. Nagamine et al [5] showed that malrotation of components in TKA is associated with poor clinical outcomes. Rotational malalignment between the femoral and tibial components can be a cause of polyethylene wear, particularly in conforming knee designs [6], causing rotational incongruity between femoral and tibial components, resulting in increased contact stresses along the tibia during flexion or extension depending on component malposition [3]. Figgie et al [7,8] outlined criteria for proper axial alignment in TKA and concluded that component rotation was an important factor. Although axial and rotational alignment are recognized as critical factors influencing TKA outcome, only axial alignment has been studied extensively because, in contrast to rotational alignment, axial alignment can be measured readily from standing long-leg radiographs [2,7–22].

- Page 765

- Berger et al [1,24] have investigated clinically the use of CT scan in determining component rotation and showed that excessive internal rotation of femoral and tibial components was associated with an increased incidence of patellofemoral complaints in patients. Their CT protocol is based on the surgical epicondylar axis and tibial tubercle as landmarks.

- Page 765

- For femoral component analysis, the surgical epicondylar axis was used as the anatomic reference because it is used by most contemporary alignment techniques to properly rotate the femoral component [25]. The technique used in this study employed the femoral component pegs to mark the component's geometric axis, which was then compared with the anatomic epicondylar axis to determine the precise femoral component rotation. Because some knee systems do not contain pegs, a different component reference point, such as posterior condylar angle [1,24], can be employed. It also is possible that difficulty may arise in identifying the epicondylar axis on CT scans without K-wire references. Previous clinical studies have not encountered this problem [1,24], however. For tibial component analysis, the posterior tibial axis was used as the anatomic reference point. The implant reference point was a tangential line to the posterior aspect of the tibial component. The angle formed between the intersection of these lines was recorded as the degree of tibial component rotation. In cases in which the posterior tibial axis cannot be defined, as in severely arthritic knees, the tibial tubercle can be used as the anatomic reference point or more reliably, the transtibial axis [1,24,26,27].

A person of ordinary skill in the art would have been motivated to combine the teachings of Jazrawi with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Jazrawi and many of the Defendants' identified references come from the same field—knee arthroplasty. Furthermore, Jazrawi teaches that proper rotational alignment is important for the proper functioning of the knee and reduces the risk of revision surgery. *See, e.g.*, Jazrawi at Abstract (“The preoperative assessment of implant rotational alignment is critical in planning treatment because the femoral or tibial component (or both) may need to be revised if malpositioned.”); 761 (“Patellofemoral complications (eg, patella subluxation or dislocation, patellar clunk, wear or loosening of the patellar component, and patella fracture) are the most common complications after total knee arthroplasty (TKA), occurring in 30% of cases [1,2]. Poor patella tracking or dislocation can be the result of malrotation of the tibial or femoral components (or both),Malrotation also causes rotational incongruity between femoral and tibial components, resulting in increased contact stresses along the tibia during flexion [3].”); 765 (“Berger et al [1,24] have investigated clinically the use of CT scan in determining component rotation and showed that excessive internal rotation of femoral and tibial components was associated with an increased incidence of patellofemoral complaints in patients. Their CT protocol is based on the surgical epicondylar axis and tibial tubercle as landmarks.”). Furthermore, Jazrawi teaches that internal/external rotation can be set by the drill holes for the pegs of an implant. *See, e.g.*, Techiera at 762 (“Femoral component rotation was measured as the angle formed between a 0.062-mm Kirschner wire (K-wire) placed in the epicondylar axis of the femur, as described by Berger et al [4] and a second K-wire secured to the top of the inner pegs of the femoral component with polymethyl methacrylate to mark its geometric center (Fig. 1). Tibial component rotation was determined from the angle formed between a K-wire fixed with polymethyl methacrylate to the posterior aspect of the tibial component and a second K-wire (secured with stainless steel tacks) 2 cm below the joint line along the posterior

condyles of the tibial specimens (Fig. 2).”). Thus, to the extent not already disclosed, a POSITA would have been motivated to position a prosthesis and thus the drill hole(s) for the peg(s) of the prosthesis based on a predetermined internal/external rotation angle.

v. Eckhoff et al.

- Abstract

- This study documents the malrotation between the femoral and tibial components associated with contemporary alignment techniques that position the tibial component relative to the tubercle, posterior tibial condyles, transtibial axis, and malleoli. The technique that allows the tibial component to float into alignment as the knee is passed through a range of motion and the technique of coupling the tibial component to the femoral component also were assessed. The average external rotation of the tibial component relative to the femoral component associated with each alignment technique is 19° (tibial tubercle), 5° (transtibial axis), 7° (posttibial axis), 3° (malleolar axis), and 14° (range-of-motion technique). The coupled-component technique produced 2° internal rotation. The observed tendency to externally rotate the tibial component relative to the femoral component with most alignment techniques may account for the high incidence of posteromedial polyethylene wear reported in retrieval studies.

- Page 28

- Two decades ago, Coventry² and Lotke and Ecker⁸ established that axial alignment was a significant factor in determining the longevity of implants in total knee arthroplasty. Since that time, the focus has remained on axial alignment, or alignment in the coronal plane of the knee, with relatively less attention paid to rotational alignment, the alignment of components in the horizontal plane of the knee. This relative inattention to rotational alignment has occurred despite that femoral and tibial components have a well-defined transverse axis by virtue of their symmetric design and malrotation, that is, rotation of the transverse axis of 1 implant relative to the other will affect the mechanics and wear of the implant within the limits imposed by the constraint or conformity of the implant design.

- Page 28-29

- The potential for implant malrotation as a result of morphologic characteristics unique to the osteoarthritic knee was identified by Eckhoff et al.³ Figgie et al⁵ identified rotational malalignment as a factor in the failure and revision of total knee arthroplasty, noting that malrotation is difficult to identify clinically. This difficulty of identifying rotation clinically may account for the paucity of studies addressing malrotation. In the laboratory, Yoshii and Whiteside¹⁰ showed that

rotational malalignment of the tibial tray has biomechanical disadvantages. Also in the laboratory, Anouchi et al¹ showed that femoral component rotation may improve patellar tracking. Finally, recent retrieval studies showed patterns of polyethylene wear that reflect the malrotation of the tibial component with respect to the femoral component.^{7,9}

- Page 29

- The rotation of the femoral component was set at 3° external rotation relative to the posterior femoral condyles. The level of tibial resection was determined precisely by a calibrated tensor jig to accept a 10-mm-thick tibial component and a 65-mm thick-femoral component.

The tibial component was positioned using 6 rotational alignment methods. Four methods relied on alignment to anatomic references, including the tibial tubercle, the posterior tibial axis, the transtibial axis, and the malleolar axis. The fifth technique relied on the tibial implant seeking its own rotational alignment as the knee was placed through a range of motion (ROM). The sixth technique involved coupling the tibial component to the femoral component with the aid of the tensor jig.

The tibial tubercle alignment technique was accomplished by pointing the imaginary front-center of the implant at the tubercle. The posterior-tibial alignment technique oriented the implant to the axis defined by the 2 most posterior points of medial and lateral tibial condyles. The transtibial alignment technique positioned the long axis of the component parallel to the imaginary bisector to the tibial plateau to provide maximal coverage of the plateau. The malleolar alignment technique oriented the tibial component relative to the malleolar axis defined by the line joining the 2 most distant points of the medial and lateral malleoli. This technique requires a jig constructed on the assumption that there is 30° internal rotation from distal to proximal tibia (tibial torsion). The ROM technique was accomplished by placing the tibial component in 30° external rotation relative to the femoral component, following which the knee was flexed and extended fully through a complete ROM 6 times. In the coupled-component technique, the tensor jig was set flat on the anterior and distal femoral cuts and the soft tissues were tensed by placing equal load on medial and lateral sides of the jig with the knee in extension. The rotation of the tibia relative to the femur is fixed when the ligaments are taut and the knee is extended (see Discussion). A block attached to the tensor jig and square to the distal femoral cuts was pinned to the anterior aspect of the tibia to provide a rotational reference on the tibia and establish the rotation of the tibial component relative to the femoral component.

- Page 29

- The average external rotation of the tibial component relative to the femoral component associated with each alignment technique is $19^\circ \pm 3^\circ$ (tibial tubercle), $5^\circ \pm 4^\circ$ (transtibial axis), $7^\circ \pm 5^\circ$ (posttibial axis), $3^\circ \pm 9^\circ$ (malleolar axis), and $14^\circ \pm 4^\circ$ (ROM technique). The coupled-component technique produced $2^\circ \pm 2^\circ$ internal rotation (Fig 1).

- Figure 1

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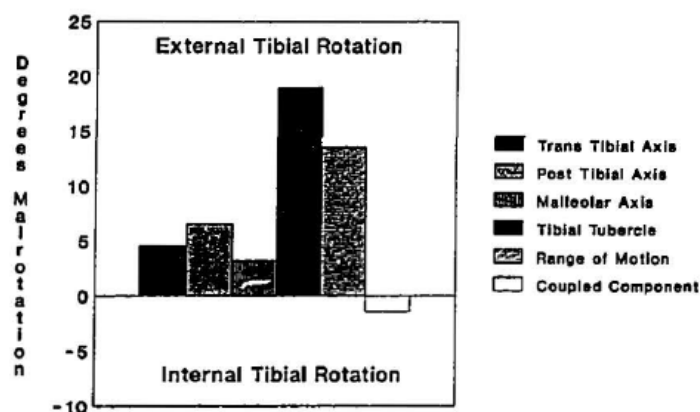


Fig 1. Tibial component malrotation relative to the femoral component associated with contemporary alignment techniques.

- Page 30

- For most of the contemporary alignment techniques, the femoral component is aligned to the anatomic landmarks of the femur (condyles, epicondyles) and the tibial component is aligned to anatomic landmarks on the tibia (tubercle, plateau, malleoli).

A person of ordinary skill in the art would have been motivated to combine the teachings of Eckhoff with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize Eckhoff teaches the importance of rotational alignment. *See, e.g.*, Eckhoff at 28 ("This relative inattention to rotational alignment has occurred despite that femoral and tibial components have a well-defined transverse axis by virtue of their symmetric design and malrotation, that is, rotation of the transverse axis of 1 implant relative to the other will affect the mechanics and wear of the implant within the limits imposed by the constraint or conformity of the implant design."). Furthermore, Eckhoff teaches multiple methods of rotationally aligning an implant. *See, e.g., id.* at 29 ("The rotation of the femoral component was set at 3° external rotation relative to the posterior femoral condyles. The level of tibial resection was determined precisely by a calibrated tensor jig to accept a 10-mm-thick tibial component and a 65-mm thick-femoral component. The tibial component was positioned using 6 rotational alignment methods. Four methods relied on alignment to anatomic references, including the tibial tubercle, the posterior tibial axis, the transtibial axis, and the malleolar axis. The fifth technique relied on the tibial implant seeking its own rotational alignment as the knee was placed through a range of motion (ROM). The sixth technique involved coupling the tibial component to the femoral component with the aid of the tensor jig."). Given that Eckhoff teaches the importance of rotational alignment and methods of setting rotational alignment, a person of ordinary skill in the art therefore would have had a reason to first determine an appropriate rotational angle of the implant and then design a guide with appropriately positioned and oriented guide holes so that positioning holes for the femoral and/or tibial implants can be drilled at the right knee position in the right orientation to provide the desired angle of rotation for the implants.

vi. PFC Sigma System (DPY_00009219 to DPY_00009477)

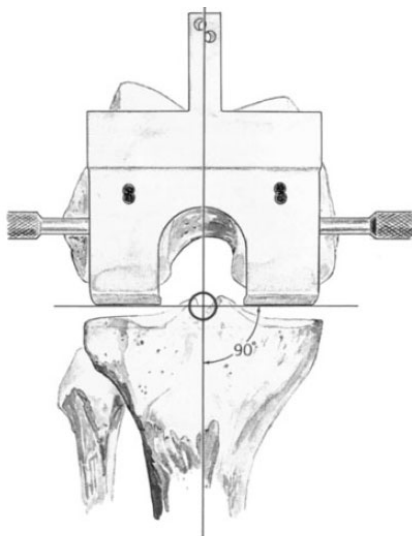
- DePuy, *P.F.C Sigma Knee System: Primary Cruciate-Retaining and Cruciate-Substituting Procedures* (2000) at 15

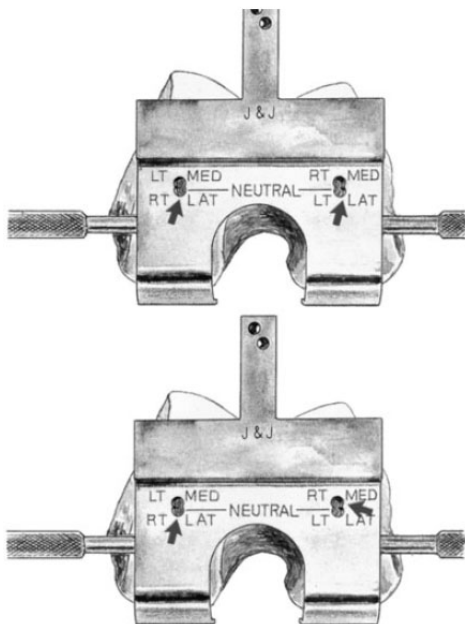
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ROTATIONAL ALIGNMENT

The sizing (drill) guide skids are positioned against the posterior condyles. This determines rotational alignment. Where either condyle is deficient, the guide is rotated such that it lies perpendicular to the mechanical axis of the tibia.

NB Alternatively, the tibia may be prepared first, wherein the A/P femoral cuts are based on the relationship of the condyles to the prepared tibial surface.





Where the guide is pinned in neutral rotation using the posterior holes, it will position the A/P cutting block such that 8 mm will be resected from the posterior condyle, corresponding to the posterior dimension of the prosthesis.

Where, as in most cases, the tibia is resected at 90 degrees to its mechanical axis, the femoral component is positioned in ~3 degrees of external rotation to produce flexion-gap symmetry. Accordingly, the lateral posterior and medial anterior holes are selected, yielding 8 mm lateral and 10-11 mm medial resection. The cutting block, thus positioned, will yield a cut in 3 degrees of external rotation, promoting flexion-gap symmetry, and enhancing patellar tracking. It will reduce soft-tissue release for tight medial flexion gap and allow commensurate rotation of the tibial component.

Occasionally, more than 3 degrees of external rotation is indicated for flexion-gap symmetry. Following removal of peripheral osteophytes, with 90 degrees of flexion and the collateral ligaments tensed with laminar spreaders, the external tibial alignment device is positioned with its upper platform raised to the level of the holes made through the sizing (drill) guide, which should lie parallel to the platform. Where more external rotation is indicated, the medial hole is repositioned anteriorly. In valgus deformity with lateral condylar hypoplasia, the lateral hole is repositioned posteriorly.

- See *also* Page 35.

A person of ordinary skill in the art would have been motivated to combine the teachings of the PFC Sigma System with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, the PFC Sigma System and many of the references identified in Defendant's Invalidity Contentions, including the Charted References, come from the same field of invention—instruments to perform total knee arthroplasty. Furthermore, the PFC Sigma System teaches that one of the criteria for “successful TKR” is “accurate patellar tracking” through “accurate position of the femoral and tibial components.” Thus, a POSITA would be motivated to apply the teachings of the PFC Sigma System to any of Defendants' identified references and design a tool wherein the position and/or orientation of the guide holes is based on a predetermined rotation angle of an articular repair system, at least under the construction implicit in Conformis's infringement contentions.

vii. Scuderi & Tria

- Page 177-178

- **PRINCIPALS OF INSTRUMENTATION . . .**

The preceding discussion has only considered the angular relationship of the femur and the tibia in the coronal plane. The instruments must align each component in the sagittal, coronal, and horizontal planes. The femoral component should include a valgus angle of 4 to 6 degrees, should be centered on the end of the femoral shaft with respect to the anteroposterior plane, should not be significantly flexed or extended, and should include external rotation of 3 to 4 degrees.

The femoral valgus angle can be referenced with respect to the femoral shaft. The anterior to posterior position and the external rotation can be verified with respect to the posterior condylar axis, the anterior cortex of the shaft of the femur, the intramedullary canal, the epicondyles, and the flexion gap. Each of the references has an individual variability. The posterior femoral condyles are easily defined. However, as the varus or valgus deformity of the knee increases the posterior aspect of the medial condyle (in varus) and the lateral condyle (in valgus) can become deficient. With this atrophy, the anterior to posterior thickness will be underestimated and the femoral cuts will be internally rotated in the valgus deformity and externally rotated in the varus deformity if the posterior condylar axis is the primary reference (Fig. 24.2). The anterior cortex of the femur is readily available for referencing.⁵ Because the lateral femoral condyle rises higher than the medial condyle in the femoral sulcus area, the surgeon must choose between the high lateral referencing or the low medial referencing. If the anterior cut is elevated, the forces in the patellofemoral joint will be increased because of the increased distance of the patella from the center of rotation of the knee. Anterior positioning of the femoral component will also increase the flexion space. If the cut is lowered on the anterior surface, there is the chance of femoral notching. A notch defect of 1 or 2 mm is probably not significant; however, deeper defects can be associated with supracondylar fracture. If all femoral cuts are referenced from the anterior cortex despite the size of the chosen component, the smaller component will increase the flexion gap, perhaps out of proportion to the extension gap, and may remove an undesirable amount of bone. The larger femoral component will decrease the flexion gap without a proportionate effect on the extension space (Fig. 24.3).

• Figure 24.2

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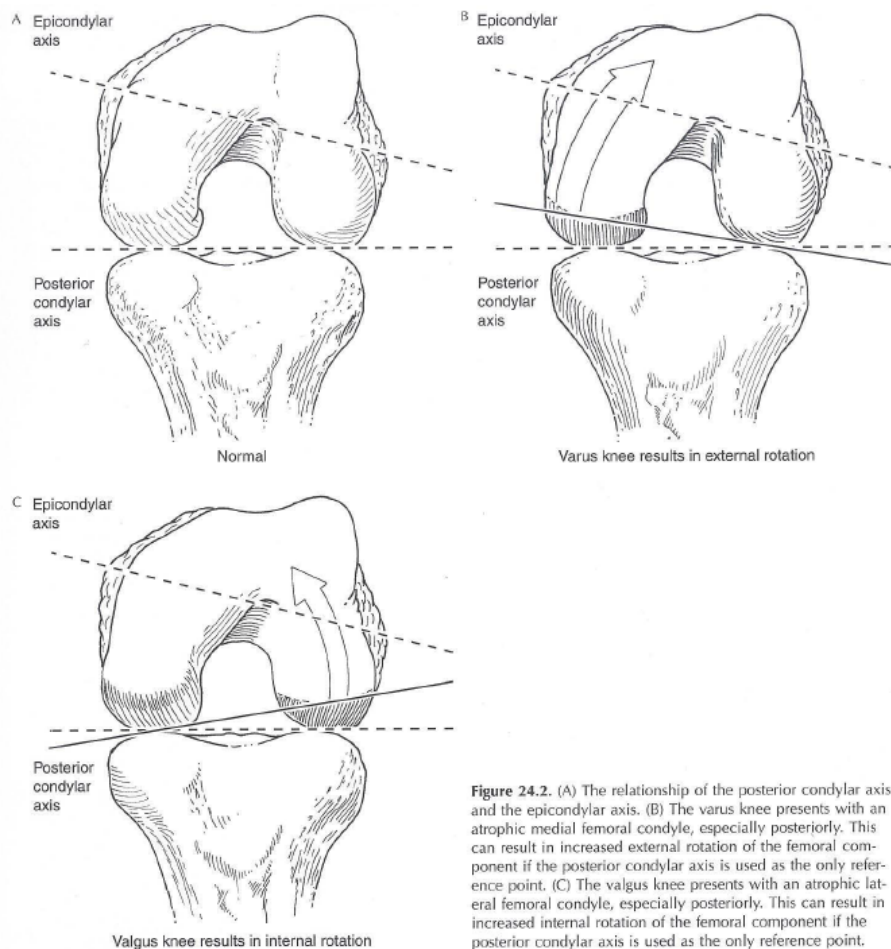


Figure 24.2. (A) The relationship of the posterior condylar axis and the epicondylar axis. (B) The varus knee presents with an atrophic medial femoral condyle, especially posteriorly. This can result in increased external rotation of the femoral component if the posterior condylar axis is used as the only reference point. (C) The valgus knee presents with an atrophic lateral femoral condyle, especially posteriorly. This can result in increased internal rotation of the femoral component if the posterior condylar axis is used as the only reference point.

- Page 178

- The epicondyles are especially helpful with respect to rotational positioning; however, it is sometimes difficult to identify the exact center point, most especially of the medial epicondyle.^{6,7} Rubash has reported some excellent anatomic studies comparing the epicondylar axis with the posterior condylar axis and he has shown that they do indeed correlate with each other.⁸ The transepicondylar axis of the distal femur does represent a reproducible landmark. The epicondyles are identified and the component is rotated until it is parallel to the axis. This reference is based solely upon the femoral anatomy, much the same as the posterior condyles. The surgeon should not confuse the rotational positioning of the femoral component with the flexion-extension gap in reference to the tibial component. With this technique the balancing is considered as a completely separate issue. The flexion gap technique for femoral rotation is based upon the reference to the tibial cut with the collateral ligaments balanced in flexion. The knee is distracted in flexion after the tibial cut has been completed. The collateral ligaments are balanced equally and the posterior femoral cut is made parallel to the proximal tibial cut surface to create a rectangular space (the "gap" technique as described by Insall) (Fig. 24.4).⁹ This technique assures ligament balance in flexion but if either collateral is abnormally tight or lax, the femoral rotation can be incorrect and interfere with patellar tracking.

The rotational alignment of the femoral component effects both the tracking of the patella and the balance of the collateral ligaments in flexion. The sulcus of the femoral component must articulate with the patella and maintain normal contact from extension to full flexion. Internal rotation of the femoral component will allow the patella to track laterally with respect to the femoral sulcus. Internal rotation will also tighten the medial flexion space and open up the lateral flexion space gap. External rotation of the femoral component favors the tracking of the patella; however, if the external rotation is excessive, the patella can track medially and the flexion gap can become too large on the medial side and too small on the lateral.

- Page 180

- The tibia must also be rotated in the horizontal plane with respect to the tibial tubercle.^{6,7} The tibial rotation is slightly less complicated than the femoral (Fig. 24.4). The tibial tubercle is the major landmark for referencing. Most component systems center upon the tubercle unless there is a marked external or, less commonly, internal rotation of the tibial tuberosity. With abnormal tubercle anatomy, the tibial rotation is usually determined with respect to the femoral component in the flexed position and then referenced in extension to check the entire range of motion. It can become difficult to choose the proper position when the existing tubercle is markedly rotated. If the tibial tray is internally rotated, the patella will track with the

patellar ligament and tend to shift laterally. If the tray is externally rotated, the patella will track more centrally but the tibiofemoral contact will not be anatomic and the rotational torque can lead to loosening or wear.

- See also pages 226-253

A person of ordinary skill in the art would have been motivated to combine the teachings of Scuderi & Tria with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Scuderi & Tria teaches that "instruments [for total knee arthroplasty] must align each component in the sagittal, coronal, and horizontal planes," *see, e.g.*, Scuderi & Tria at 177, and that proper rotational alignment of the femoral and tibial components is important for proper functioning of the resulting implant. *Id.* at 178 ("The rotational alignment of the femoral component effects both the tracking of the patella and the balance of the collateral ligaments in flexion. The sulcus of the femoral component must articulate with the patella and maintain normal contact from extension to full flexion. Internal rotation of the femoral component will allow the patella to track laterally with respect to the femoral sulcus. Internal rotation will also tighten the medial flexion space and open up the lateral flexion space gap. External rotation of the femoral component favors the tracking of the patella; however, if the external rotation is excessive, the patella can track medially and the flexion gap can become too large on the medial side and too small on the lateral."); 180 ("If the tibial tray is internally rotated, the patella will track with the patellar ligament and tend to shift laterally. If the tray is externally rotated, the patella will track more centrally but the tibiofemoral contact will not be anatomic and the rotational torque can lead to loosening or wear."). Scuderi & Tria teaches that femoral instruments can be aligned with respect to the epicondylar axis and tibial instruments with respect to the tibial tubercle to ensure proper rotational alignment. *Id.* at 178 ("Rubash has reported some excellent anatomic studies comparing the epicondylar axis with the posterior condylar axis and he has shown that they do indeed correlate with each other.⁸ The transepicondylar axis of the distal femur does represent a reproducible landmark. The epicondyles are identified and the component is rotated until it is parallel to the axis. This reference is based solely upon the femoral anatomy, much the same as the posterior condyles."); 180 ("The tibial tubercle is the major landmark for referencing."). Thus, a POSITA would be motivated to align the tool guides of a patient-specific template with respect to an anatomical feature or axis.

viii. Insall

- Pages 1556-1557
 - Proper femoral rotation is essential because inappropriate femoral component rotation may result in flexion imbalance and patellofemoral problems.^{6, 10, 122} Although an arbitrary predetermined external rotation of 3 degrees is often satisfactory,^{47, 123} several methods have been developed in an effort to accurately determine appropriate femoral rotation (Fig. 74.11):

1. Medial and lateral epicondyles.^{11,118}
2. Posterior femoral condyles.⁵⁸
3. Anteroposterior femoral axis (“Whiteside’s line”).^{7,168}
4. Tibial shaft axis.¹⁵¹
5. Ligament tension.

Femoral rotation is difficult to instrument precisely because of landmark inconsistencies and obscurities; the surgeon must form her or his own judgment, making sure to err on the side of external rotation, never internal rotation.^{6,10,122}

The posterior condylar axis is frequently used as the reference for femoral rotation; however, posterior condylar erosion as part of the arthritic process often distorts this reference angle, and so it should probably not be relied on as the sole method of determining femoral rotation.^{58, 151} The anteroposterior axis of the femoral sulcus, described by Whiteside,^{7, 168} has also been shown to be an accurate reference point for determining femoral rotation; however, it has been shown to be less reliable in cases of trochlear dysplasia and some valgus knees.¹¹⁸ The tibial shaft axis has also been described as an effective reference axis for defining femoral rotation.¹⁵¹ Using the anatomic axis of the tibia is particularly useful because it should facilitate balancing the flexion space when perpendicular proximal tibial cuts are used for total knee arthroplasty (TKA).

We use the epicondylar axis to most closely recreate the patient’s natural femoral rotation.^{11, 118} Identifying the epicondylar axis requires some additional soft-tissue dissection to define the anatomic positions [sic] of the medial and lateral epicondyles. The center of the medial epicondyle is located in the sulcus, which lies between the proximal origin of the superficial deep medial collateral ligament (MCL) and the distal origin of the deep MCL. The medial epicondylar ridge at the origin of the superficial MCL can be identified by isolating the condylar vessels that lie proximal and anterior to the medial epicondylar ridge. From these vessels the epicondylar ridge can readily be outlined; the center of this outline is the sulcus, which can typically be palpated (Fig. 74.12). The lateral epicondyle is the most prominent point on the lateral aspect of the distal femur. Here, too, following the leash of condylar vessels confirms the exact location of the lateral epicondyle that lies immediately distal to the vessels (Fig. 74.13).

The benefit of having several different methods of assessing femoral rotation is that one or more can be used to confirm the surgeon’s preferred method (Fig. 74.14) . Several investigators have compared these various methods. Poilvache et al¹¹⁸

correlated the transepicondylar, anteroposterior, and posterior condylar axes. Berger et al¹¹ and Griffin et al⁵⁷ described the relationship of the epicondylar axis to the posterior condylar axis. Whiteside^{7, 168} defined the relationship of the anteroposterior and posterior condylar axes. Finally, Stiehl et al¹⁵¹ demonstrated that referencing from the tibial shaft axis is more accurate than referencing from the posterior condylar axis.

- Figure 74.11

○

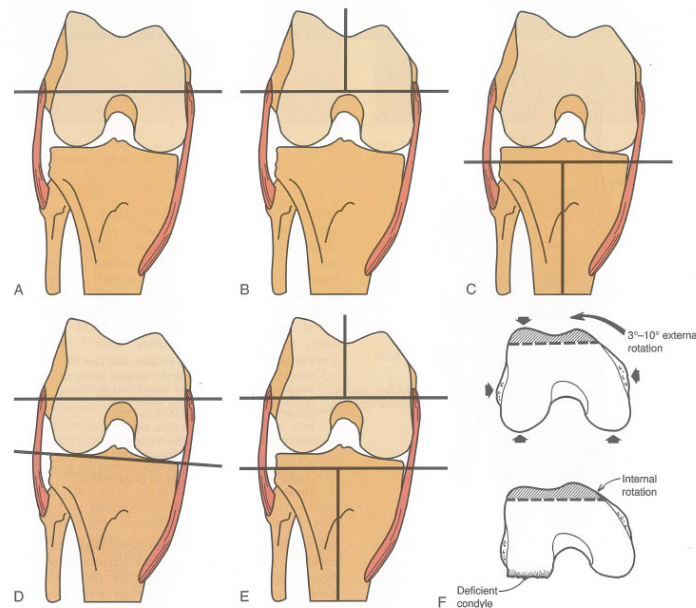


FIGURE 74.11 > Reference points for rotational positioning of the femoral component are the epicondyles, the trochlear surface, the tibial shaft, and the posterior condyles. A. The transepicondylar axis. B. The anteroposterior trochlear sulcus ("Whiteside's line"). C. The tibial shaft axis. D. The posterior condylar axis. E. The transepicondylar axis is perpendicular to the anteroposterior sulcus line and the tibial shaft axis. F. When the posterior condyles are used for rotational reference, one must beware of erosion of the condyles. For example, in valgus knees, posterior erosion of the lateral femoral condyle is often present, which may result in internal rotation of the femoral component.

- Pages 1582-1583

- The distal femoral osteotomy is made by removing precisely the amount of bone that will be replaced by the femoral prosthesis. Some systems measure this amount from the uninvolved condyle, whereas others key off the medial femoral condyle regardless of the knee pathology (see Fig. 74.24).

The distal femur is then sized, and anterior and posterior femoral resections are made, using appropriate templates (Fig. 74.54). Rotational alignment, if not already done at an earlier stage, is adjusted when positioning the femoral template. We align the femoral AP cutting block with the epicondylar axis (Fig. 74.55).

- Figure 74.55

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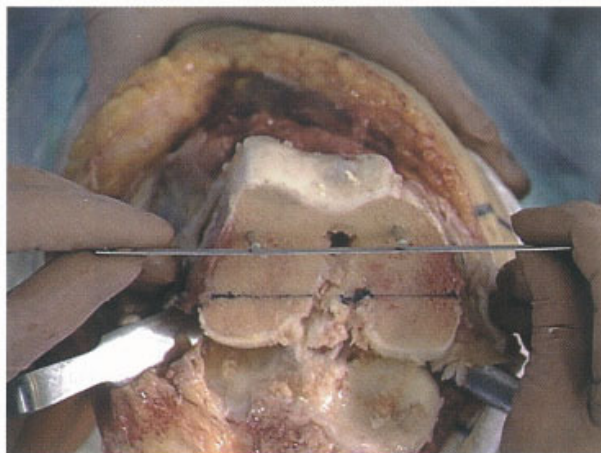


FIGURE 74.55 ➤ The instrumentation is aligned with the epicondylar axis (pins are parallel to epicondylar axis, as indicated by ruler placed across them).

A person of ordinary skill in the art would have been motivated to combine the teachings of Insall with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Insall teaches that "[p]roper femoral rotation is essential because inappropriate femoral component rotation may result in flexion imbalance and patellofemoral problems." Insall at 1556. Furthermore, Insall teaches several methods to measure internal/external rotation,

including placing the holes for the pins of an implant in relation to anatomical axis. *See, e.g., id.* at 1556-1557; Fig. 74.55. Because many of the identified references comes from the same field of invention as Insall, joint arthroplasty, particularly, total knee arthroplasty, to the extent not already disclosed, a POSITA would be motivated to position or orient drill paths in a template based on a predetermined rotation angle of a prosthesis.

J. Osteophyte Limitations

Referencing and/or accommodating an osteophyte, including as recited in the following Asserted Claims, was well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
482	1	wherein the corresponding portion of the diseased or damaged joint includes an osteophyte, wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and
482	17	wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint; and
780	5	The system of claim 1, wherein the anatomic relief accommodates one or more osteophytes of the joint.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art
 - i. Ex Parte Re-Examination of '482 Patent, Reply Dated July 18, 2018¹¹

¹¹ In the quotes from the Reply dated July 18, 2018, all citations to Exhibits have been omitted.

- Pages 6-7

- In some patients, bony outgrowths called osteophytes form in an attempt to counteract the loss of articular cartilage. In the knee joint, osteophytes fall into one of two categories: marginal osteophytes or central osteophytes. Although an adaptive response to counteract cartilage degeneration, both marginal and central osteophytes are a nuisance that can adversely affect the knee joint.
- Marginal osteophytes are an attempt to increase the size of the joint to reduce the load or otherwise fuse the joint to prevent movement and stop pain. Marginal osteophytes form as chondrocytes (cartilage cells) that subsequently undergo endochondral ossification to become bone tissue. Fully formed marginal osteophytes comprise a thin layer of cortical bone around a core of cancellous bone (relatively porous and spongy bone). They are irregular in shape, often aggregating and forming what look like miniature mountain ranges. As marginal osteophytes extend out from the bone surface, they interfere with surrounding tissues, including the medial and lateral collateral ligaments. In doing so, they stretch, tear, or even rupture the ligaments, causing further pain and inflammation and jeopardizing joint stability and strength. Although marginal osteophytes have a hard thin shell of cortical bone, they are easily removed using manual tools such as curettes, rongeurs, and osteotomes.

- Pages 9

- Knee arthroplasty techniques have changed little since the introduction of intramedullary and extramedullary rods. Instead, improvements have been made to the orthopedic implants themselves. . . . Osteophytes that may have grown in the knee joint are necessarily (and importantly) removed as part of "ligament balancing" to ensure proper alignment, joint tightness, and articulation of the implanted system. If they are not removed, they prevent proper implant fit or alignment, and impinge on ligaments (and other soft tissue), adversely affecting joint stability. *Id.* The osteophytes may be removed before resecting the femur or tibia (and placing the cutting guide) or afterwards, but they are always removed.

ii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

- Paragraphs 17-19

- In patients with cartilage degeneration, osteophytes (also known as bone spurs) are often, but not always, present. Osteophytes are bony projections that may form in response to cartilage degeneration and the compromised function of the knee. In particular, as cartilage degenerates, the knee joint becomes misaligned and experiences abnormal loading. In

response, the body attempts to increase the size of the joint (through osteophytes) in order to reduce the load or to fuse the joint (through osteophytes) in order to prevent movement. Osteophytes may be marginal osteophytes or central osteophytes.

Marginal osteophytes are irregular in shape and can resemble miniature mountain ranges. They range in size from 1 to several millimeters. Marginal osteophytes have a hard outer shell but have a relatively soft interior structure and are easily removed using manual tools such as curettes, rongeurs, and osteotomes.

Marginal osteophytes may adversely affect the medial and lateral collateral ligaments. The collateral ligaments extend along the sides of the femur and tibia, connecting them in relatively tight alignment. Marginal osteophytes may impinge on the medial and lateral collateral ligaments and stretch them outward. Marginal osteophytes may even become large enough to tear or rupture the ligaments or synovial membrane surrounding them. Marginal osteophytes can be seen on x-ray images and appear as irregular outgrowths of the peripheral bone surface. More advanced imaging studies (e.g., computed tomography ("CT") imaging or magnetic resonance ("MRI") imaging), however, are needed to discern the approximate shape, size, and location of a marginal osteophyte.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught patient-specific surfaces referencing and/or accommodating one or more osteophytes. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that having a patient-specific surface referencing and/or accommodating osteophytes can provide certain benefits. Furthermore, the Charted References taught that having a patient-specific surface, which may reference and/or accommodate an osteophyte, can increase the accuracy of the work done to the bone. Finally, many of the Charted References come from the same field of invention—tools for total knee arthroplasty. Thus, a POSITA would have been motivated to combine the Charted References to include a patient-specific surface that references and/or accommodates an osteophyte.

3. Additional References

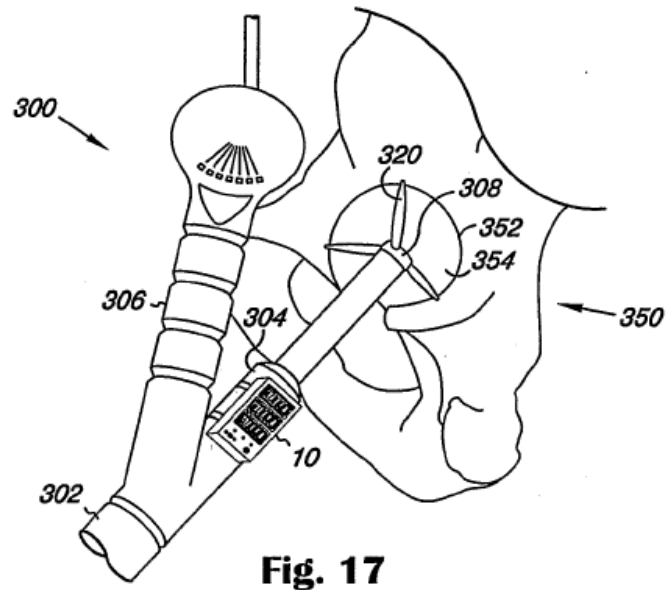
The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Stone

- Paragraph [078]
 - As shown, the alignment guide 308 includes a body portion 318 and wings or arms 320a, 320b, and 320c, which are disposed generally in the same plane. The body portion 318 includes internal threads 316 for mating with the support shaft 304. In one embodiment, the arms 320 are secured at points 320 degrees apart around the circumference of the body portion 318 by pivots 324a, 324b, and 324c. The pivots 324 allow for slight in-plane rotation of the arms 320 where necessary, for example to avoid contact with an anatomical aberration as the lip of the acetabulum.
- Paragraph [083]
 - According to one embodiment, as described above, the arms 320 are adjusted in length by the surgeon using a telescoping action. In another embodiment, the surgeon may need to pivot the arms 320 to avoid an osteophyte or other surface aberration on the rim 352 of the acetabulum 354.

- Figure 17

-



- Paragraph [091]

- The guide 510 is placed on the rim of the glenoid, such that the upper arm is placed at the most superior position of the rim, and the anterior and posterior arms are generally aligned in the center of the superior/posterior glenoid (block 558). Again, the arms may be adjusted to avoid significant osteophytes.

- Paragraph [092]

- In yet another embodiment, the device 10 is used by a surgeon to facilitate TKA.

A person of ordinary skill in the art would have been motivated to combine the teachings of Stone with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the teachings in Stone could be applied to templates for other types of orthopedic interventions, such as total knee arthroplasties. *See, e.g.*, Stone at [0091] ("In yet another example, the device 10 is used by a surgeon to facilitate TKA."). Furthermore, Stone teaches that applying its approach to total knee arthroplasties could yield benefits, including more accurate alignment of the resection guides and ultimately an implant. *Id.* at [0091] ("For TKA, the device 10 may be affixed to the initial guides commonly used by surgeons, to enable more accurate alignment than that provided by the existing guides. In various exemplary embodiments, the device 10 can be affixed to the cutting blocks to provide more accurate rotational alignment, varus/valgus alignment, and level of resection."). A person of ordinary skill in the art would have been motivated to combine the teachings of Stone with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References, as Stone taught that "[c]orrect positioning of surgical instruments and implants, used in a surgical procedure, with respect to the patient's anatomy is often an important factor in achieving a successful outcome," and that avoiding an osteophyte can be necessary in some situations. *See, e.g., id.* at [0002]; [0077] ("The pivots 324 allow for slight in-plane rotation of the arms 320 where necessary, for example to avoid contact with an anatomical aberration as the lip of the acetabulum."); [0082] ("In another example, the surgeon may need to pivot the arms 320 to avoid an osteophyte or other surface aberration on the rim 352 of the acetabulum 354."). A person of ordinary skill in the art would have been motivated to apply Stone's teachings, including the teaching of avoiding osteophytes to other types of joint arthroplasty such as TKA because it was understood that there are irregularities on joint surfaces, such as bone spurs (i.e., osteophytes). *See* Berez at [0182]; *see also* Insall, ARTHRITIS OF THE HIP & KNEE and OSTEOARTHRITIS HANDBOOK below. Finally, a person of ordinary skill in the art would recognize that Stone and many of the Charted References are from the same field of invention. *Id.* at [0001] ("The present invention relates to medical orientation and positioning devices and in particular to a device for orienting surgical instruments, implements, implants, prosthetics, and anatomical structures."). Thus, to the extent not disclosed, a POSITA would have been motivated to design a tool/template to reference an osteophyte, including to accommodate or avoid an osteophyte.

ii. Radermacher Thesis

- Figure 4-24

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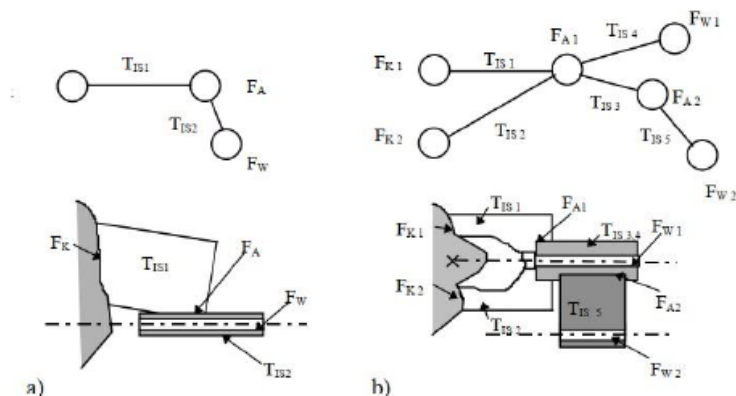


Figure 4-24: Examples of different connection structures of customized templates (cf. [Koller 1994], p. 60): a) simple customized template with one contact, alignment and tool guide surface each and template element as connection structure; b) template with several contact, alignment and tool guide surfaces; the standardized partial elements $T_{IS\ 3,4,5}$ reproduce an intrinsic processing geometry (for example, implant-specific), the functional surfaces F_{A2} , F_{W1} and F_{W2} are in this case generally not individually adapted. Individually adapted functional surfaces are F_{K1} and F_{K2} and, if required such as for alignment and positioning, F_{A1} . The shape of T_{IS1} and T_{IS2} can be standardized or adapted to individual anatomical conditions according to requirements.

- Page 90

- The general technical structure of customized templates can thus be composed of the following elements:

- Individually adapted contact surface(s) F_{Ki} ,
- Individually adapted or standardized adapter surfaces (F_{Ai}) for aligning the tool guides, in relation to the reference
- Individual, but generally standardized tool guidance surfaces F_{Wi} , as well as a connection structure consisting of one or more individually adapted and/or standardized template partial elements $T_{IS\ i}$ (Figure 4-24).

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach patient-specific templates for total knee arthroplasty. *See, e.g.*, Radermacher Thesis at 3 ("Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen."). Radermacher Thesis also teaches that the disclosed templating technique can be applied to total knee arthroplasty, the same surgical procedure addressed by many of the references identified in Defendants' Invalidity Contentions. Thus, to the extent not disclosed a POSITA would find it obvious to apply the teachings of Radermacher Thesis to any of the references identified in Defendants' Invalidity Contentions.

iii. Insall

- Page 1020

- Arthritis of the patellofemoral joint predominantly involves the lateral joint line in the great majority of cases. The usual aspect on the axial view includes narrowing of the joint line, osteophytes of the lateral border of the patella and trochlea, subchondral sclerosis of the lateral facet, and possibly cyst formation (Fig. 46.98).

- Figure 4.62

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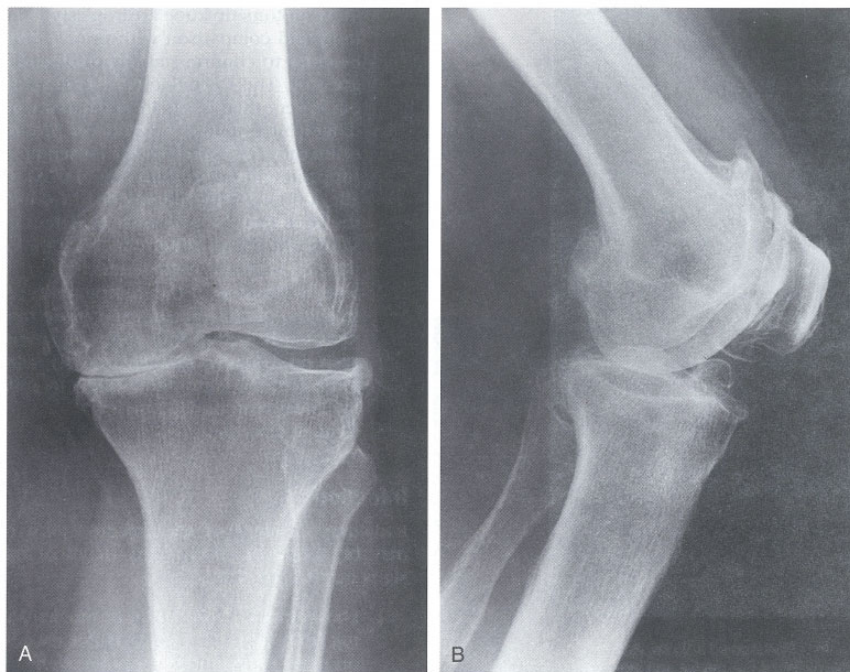


FIGURE 4.62 > Degenerative joint disease. Anteroposterior (A) and lateral (B) views of the knee show the characteristic finding of osteoarthritis. There is joint space narrowing and osteophyte formation at the medial and patellofemoral compartments with varus alignment at the knee. There is also a large suprapatellar joint effusion.

A person of ordinary skill in the art would have been motivated to combine the teachings of Insall with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Insall and many of the identified references come from the same field, *i.e.*, knee surgery, and that Insall is focused on communicating relevant information regarding knee surgery. A POSITA would also recognize that Insall teaches the anatomical conditions of the knee that should be taken into account when conducting knee surgery. Specifically, Insall teaches that osteophytes can form on the knee from osteoarthritis. Thus, a POSITA would be motivated to consider the presence of osteophytes when designing tools for total knee arthroplasty.

iv. ARTHRITIS OF THE HIP & KNEE

- Pages 12
 - Osteoarthritis is an abnormal condition that causes a joint and its surrounding structures to deteriorate to varying degrees. (See Figures 2-1 and 2-2 on the stages osteoarthritis of the hip and knee.) This degeneration in turn may cause pain and loss of function, also to varying degrees.
- Pages 13-14
 - Arthritis creates abnormalities within the structure of the joint. These abnormalities can cause the soft tissue that can cause the firm, smooth, shiny surface of the joint (the articular cartilage) to become thin and irregular. The bone under the cartilage may become very dense and stiff. Outgrowths, called osteophytes or spurs, may appear at the edge of the articular cartilage. These abnormalities within the joint cause weakness of the muscles and surrounding ligaments, joint instability, and pain.

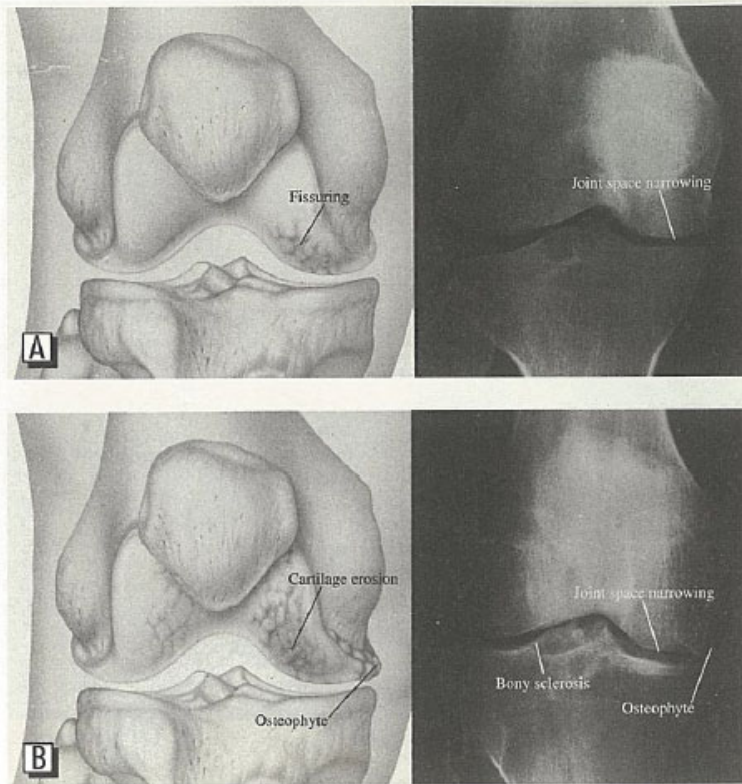
- Figure 2-2

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FIGURE 2-2
Stages of Osteoarthritis of the Knee

A. Stage I: mild osteoarthritis

B. Stage II: moderate osteoarthritis



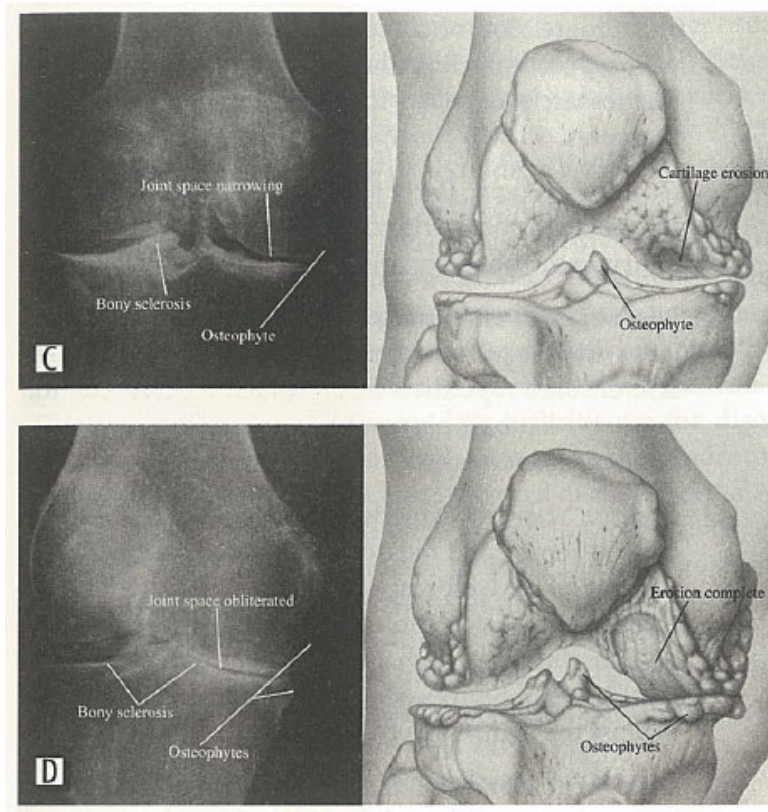


FIGURE 2-2

*C. Stage III:
moderately severe
osteoarthritis*

*D. Stage IV: severe
osteoarthritis*

- Figure 2-1

○

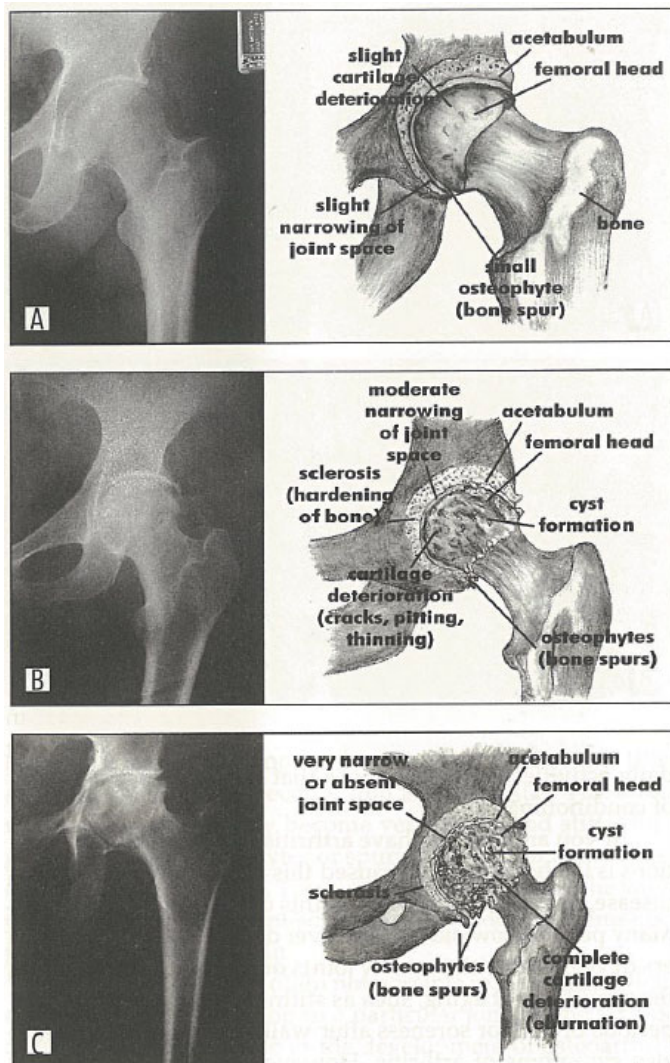


FIGURE 2-1
Stages of
Osteoarthritis
of the Hip

A. Stage I: mild
osteoarthritis

B. Stage II: moderate
osteoarthritis

C. Stage III: severe
osteoarthritis

- Page 63

- Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful.

A person of ordinary skill in the art would have been motivated to combine the teachings of ARTHRITIS OF THE HIP & KNEE with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that ARTHRITIS OF THE HIP & KNEE teaches the anatomical conditions of a joint that can be taken into account when designing tools for total joint arthroplasty. Specifically, ARTHRITIS OF THE HIP & KNEE teaches that in the advanced stages of osteoarthritis, which is when it is most often clinically indicated for patients to undergo total knee arthroplasty, there are osteophytes on the articular surfaces of the knee. *See, e.g.*, Figure 2-2; Page 63 ("Although joint replacement surgery is usually appropriate when patients have clinical symptoms and x-ray evidence of advanced arthritis, you and your orthopedic physician should not consider such surgery until you have tried all the non-surgical methods to control pain and loss of function (see Chapter 3) and found them no longer to be successful."). A person of ordinary skill in the art would understand from ARTHRITIS OF THE HIP & KNEE that osteophytes are a common occurrence in, *e.g.*, articular cartilage areas. Many of the references identified in Defendants' Invalidity Contentions are directed to tools for total joint arthroplasty, including total knee arthroplasty, thus a POSITA would be motivated to take the anatomical conditions of a typical knee undergoing total joint arthroplasty, including the presence of osteophytes, into account when designing patient-specific tools for total joint arthroplasty. For example, as explained above, a person of ordinary skill in the art would understand that surface irregularities would affect how well the contact surface of a template/mold/surgical instrument/guide conform to the bone surface. As such, they would understand that the design of the surgical instrument/guide/template/mold should take into consideration these anatomic reference points, by either engaging them or avoiding them if the osteophytes were not otherwise removed.

v. OSTEOARTHRITIS HANDBOOK

- Page 146-148

- The top of the tibia and the bottom of the femur are cushioned by glossy, shiny, "glasslike" hyaline cartilage. In this as in other joints, cartilage serves as a shock absorber. It also provides a gliding surface with minimal friction, which enables the

joint to function smoothly and effortlessly. Osteoarthritis and rheumatoid arthritis attack this cartilage, causing it to pit, buckle, and gradually erode away.

- Page 153

- **Moderate Osteoarthritis**

Progressively, osteoarthritis destroys the delicate architecture and function of the knee joint. The cartilage covering the ends of the tibia and femur wears away. The joint space narrows.

- **Severe Osteoarthritis**

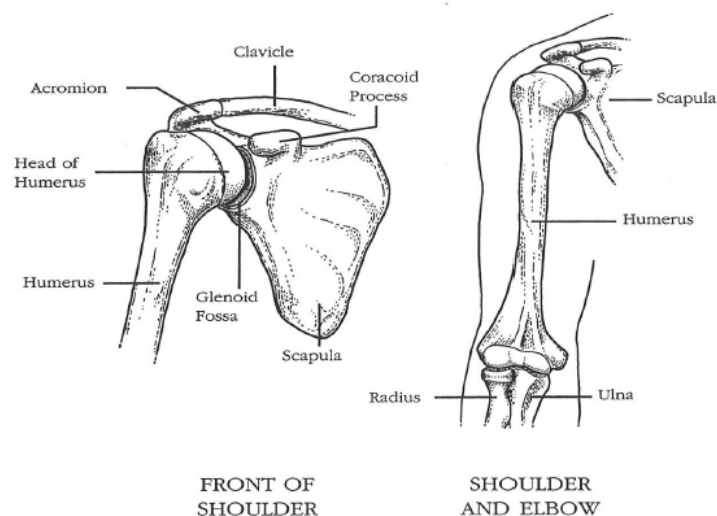
When the entire hyaline cartilage is gone and the joint space has vanished, bone rubs on bone, and any movement is excruciatingly painful. Large bone spurs, or osteophytes, may grow along the periphery of the joint. These spurs can be seen as the body's attempt to increase the area available for load bearing. They may also be the body's attempt to stiffen up the joint since less movement often means less pain. Depending on their location, these spurs can actually increase the pain.

Osteoarthritic damage is often limited to the destruction of the hyaline cartilage and the formation of bony overgrowths. There can also be a marked shortening of the tendons and ligaments, which makes it impossible for the patient to completely straighten the knee (flexion contracture).

- Figure 12-I

-

FIGURE 12-1: *The Shoulder*



The shoulder or shoulder girdle is a conglomeration of four joints that attach the arm to the trunk. The principal bones involved are the humerus (upper arm bone), the scapula (shoulder blade), and the clavicle (collarbone). The glenohumeral joint, which often develops osteoarthritis, is formed by the upper end of the humerus and the glenoid cavity of the scapula. It is a ball-and-socket joint like the hip, except that the socket—the glenoid fossa—is much shallower than the acetabulum.

- Page 195-196

- Diagnosis is complicated since the shoulder develops many aches and pains, most of them not related to arthritis. . . .

An X ray confirms a diagnosis. Early osteoarthritis is marked by joint space narrowing. As the disease progresses, the smooth hyaline surface is pitted, becoming increasingly uneven. More advanced disease is characterized by osteophyte formation. Eventually the shoulder cartilage wears out, and bone rubs on bone. (See Chapter 3 for more on the development of OA.)

A person of ordinary skill in the art would have been motivated to combine the teachings of OSTEOARTHRITIS HANDBOOK with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that OSTEOARTHRITIS HANDBOOK teaches that osteophytes can form in the advanced stages of osteoarthritis, which is when it is most often clinically indicated for patients to undergo total knee arthroplasty. *See, e.g.*, Page 153 ("When the entire hyaline cartilage is gone and the joint space has vanished, bone rubs on bone, and any movement is excruciatingly painful. Large bone spurs, or osteophytes, may grow along the periphery of the joint. These spurs can be seen as the body's attempt to increase the area available for load bearing. They may also be the body's attempt to stiffen up the joint since less movement often means less pain. Depending on their location, these spurs can actually increase the pain."). Further, many of the references identified in Defendants' Invalidity Contentions are directed to tools for total joint arthroplasty, including total knee arthroplasty, thus a POSITA would be motivated to take osteophytes into account when designing patient-specific tools for total joint arthroplasty. For example, as explained above, a person of ordinary skill in the art would understand that surface irregularities would affect how well the contact surface of a template/mold/surgical instrument/guide conform to the bone surface. As such, they would understand that the design of the surgical instrument/guide/template/mold should take into consideration these anatomic reference points, by either engaging them or avoiding them if the osteophytes were not otherwise removed.

vi. Scuderi & Tria

- Page 12

- Degenerative joint disease (DJD) of the knee is the most common condition necessitating total knee arthroplasty. Radiographic findings of DJD are usually clearly evident at the time of presentation and include cartilage loss (joint-space narrowing), subchondral sclerosis and cyst formation, and osteophyte formation² (Fig. 2.11). The joint compartments are involved with the following frequency: medial > patellofemoral > lateral.

- Page 15

- CT is of limited usefulness for preoperative evaluation; it is most helpful in complicated cases in which there is prior trauma and deformity requiring custom prosthetic components. Also, CT is helpful in cases of suspected chronic infection, for delineating the presence of a bony sequestrum. Computer-reformatted 2-dimensional and 3-dimensional images can be generated; however, these are more aesthetic than they are clinically useful (Fig. 2.14).

- Figure 2.14

○



Figure 2.14. DJD—3-Dimensional CT: 3-Dimensional reformatted image of the knee shows advanced medial compartment disease, with a ridge of osteophytes at the margins of the tibial plateau and femoral condyle.

A person of ordinary skill in the art would have been motivated to combine the teachings of Scuderi & Tria with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Scuderi & Tria and many of the identified references come from the same field, *i.e.*, knee surgery, and that Scuderi & Tria is focused on communicating relevant information regarding knee surgery. A POSITA would also recognize that Scuderi & Tria teaches the anatomical conditions of the knee that should be taken into account when conducting knee surgery. Specifically, Scuderi & Tria teaches that osteophytes can form on the knee from osteoarthritis. Thus, a POSITA would be motivated to consider the presence of osteophytes when designing tools for total knee arthroplasty.

K. “Guide Hole” Limitations

Guide holes, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff’s infringement contentions:

Patent	Claim	Claim Language
161	1	two or more guide holes, each configured to guide a surgical pin,
161	1	wherein at least one of the two or more guide holes has a position and/or orientation based on anatomical information of the joint of the patient to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with the joint of the patient,
161	19	two or more guide holes, each configured to guide a surgical pin,
161	19	wherein the position and/or orientation of at least one of the two or more guide holes includes anatomical information of the joint of the patient to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with and substantially conforms to the shape of the joint of the patient,
304	1	two or more guide holes, each configured to guide a surgical pin,
304	1	wherein at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient,
304	31	two or more guide holes, each configured to guide a surgical drill or pin,
304	31	wherein the position a of the guide hole includes anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with and substantially conforms to the shape of the cartilage surface of the joint of the patient,

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Asserted Patents

- '745 Patent, 4:38-40; '482 Patent, 4:47-50; '161 Patent, 4:45-48; '129 Patent, 4:6-9; '304 Patent, 4:6-9
 - U.S. Pat. No. 6,106,529 to Techiera issued Aug. 22, 2000 discloses an epicondylar axis referencing drill guide for use in resection to prepare a bone end for prosthetic joint replacement.

ii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor

- Paragraph 68

- *Radermacher* describes reconstructing tomographic images into a three-dimensional image of the osseous structure. *Id.* at 12. And with a computer system, a "three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure" is generated. *Id.* *Radermacher* explains that this negative mold of the bone surface can be used to construct the contact surface of the cutting guide. *Id.*

- Paragraph 69

- In addition, cutting paths may be included "in/on the basic body" of the cutting guide. *Id.* at 13. The cutting paths are oriented or constructed "relative to the [three-dimensional] reconstruction of the osseous structure" to "effect a three-dimensional guiding of the treatment tools or measuring devices exactly as provided by [preoperative] planning." *Id.* That is, the treatment steps defined in preoperative planning "can be exactly transferred since, relative to the osseous structure, the [cutting paths] can be brought exactly into the positions defined during [preoperative] planning." *Id.* at 14-15. "To this purpose, the [cutting guide] with the faces of the negative mold is set under mating engagement onto the then exposed bone surface . . . without any further intraoperative devices . . . and without intraoperative measuring and positioning work." *Id.* at 15. *Radermacher* notes that "nails, screws and the like" may be used to fix the cutting guide to the bone. *Id.* at 25.

iii. Declaration of Dr. Thomas R. Oxland ¶¶ 63-64, *Conformis, Inc. v. Medacta USA, Inc.*, No. 19-1618-RGA (D. Del. Dec. 12, 2020)

- Paragraph 52

- In addition, in “The Technique of Total Knee Arthroplasty” by Kenneth A. Krackow (“Krackow”), which I understand was published in 1990, Krackow explains that “[s]tabilizing many tibial cutting assemblies requires placing drills or pins through jigs into proximal tibial bone[.]” Krackow, 199. . . . Indeed, Krackow illustrates a “[t]ibial cutting jig” that is “fixed to [the] proximal tibia” and “held with spikes or drill pins[.]” as reproduced below:

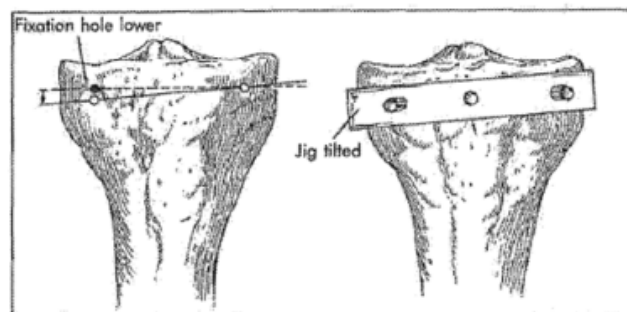
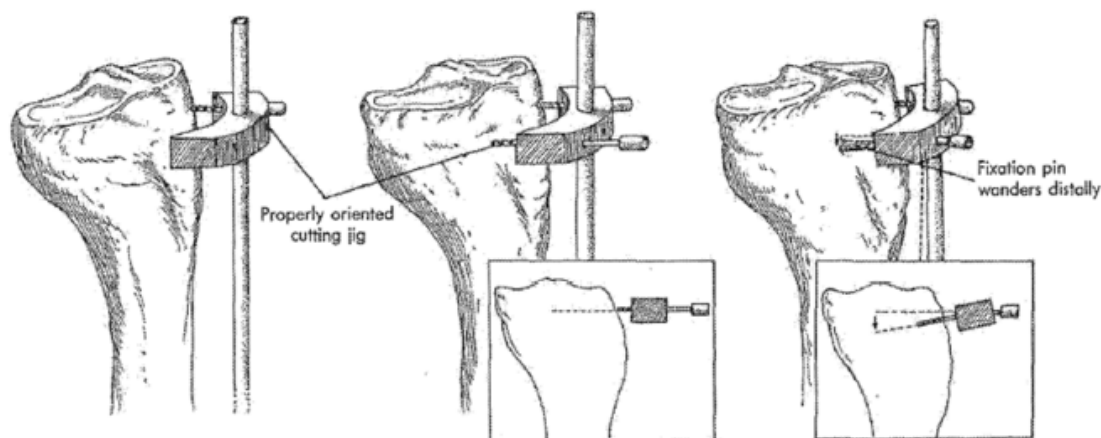


FIGURE 5-29

Id., 196.

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught two or more guide holes, each configured to guide a surgical pin, wherein the position of the guide hole includes anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, many of the Charted References come from the same field of invention—patient-specific tools for total knee arthroplasty. Furthermore, the Charted References taught that the use of two or more guide holes, each configured to guide a surgical pin, wherein the position of the guide hole includes anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient can increase the alignment of the resulting implant.

3. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.*,

i. Vomlehn

- [0026]
 - In order to properly operate a medical device on a subject, it must be stable, and located at a proper position and orientation, (pose).
- [0036]
 - Reference structure 30 may then be physically held against an anchor site 6 by the surgeon, or attached by various conventional means such as screws, pins, glue, clamps, etc. The reference structure 30 may then be used as a reference, or anchor structure for other surgical equipment.

- Figure 2

○

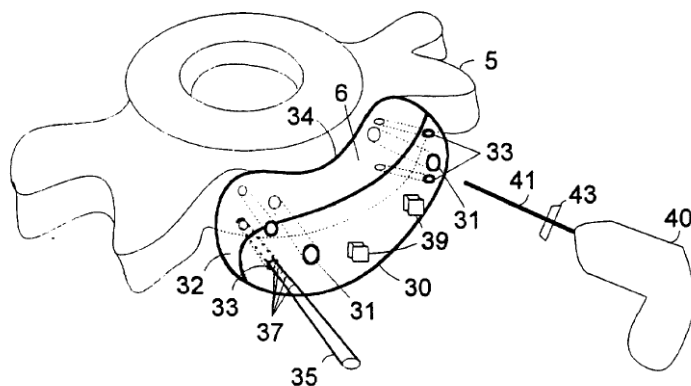


Fig. 2

A person of ordinary skill in the art would have been motivated to combine the teachings of Vomlehn with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Vomlehn teaches that "[i]n order to properly operate a medical device on a subject, it must be stable, and located at a proper position and orientation, (pose)." Vomlehn at [0026]. A POSITA would recognize that attaching the reference structure disclosed in Vomlehn to the bone using pins, is a method of stabilizing a medical device on a patient. *See, e.g.*, Vomlehn at [0036] ("Reference structure 30 may then be physically held against an anchor site 6 by the surgeon, or attached by various conventional means such as screws, pins, glue, clamps, etc. The reference structure 30 may then be used as a reference, or anchor structure for other surgical equipment."). Additionally, a person of ordinary skill in the art would recognize that the teachings in Vomlehn could be applied to a wide variety of orthopedic procedures, including total knee arthroplasty. *See, e.g.*, [0001] ("The present invention relates to computer-aided construction of a reference structure to be attached to a subject and act as a guide in medical procedures."); [0002] ("In various medical procedures, it is necessary to attach a piece of medical equipment into a solid structure of the subject."). Thus, to the extent not disclosed, a POSITA would be motivated to include one or more holes to accept a pin on a patient-specific template.

- ii. Techiera

- Abstract
 - “Preferably, a template or one or more sets of graduations constitute a sizing jig in the tool, which may determine an offset, and the drill positioning block is coupled so that it positions drill holes on the bone end in coordination with sizing jig or other offset indicators. The device allows the surgeon to confirm or change the prosthesis size with regard to landmarks, and to visualize its fit in different translated positions. The drill holes may set a position for a standard cutting block to fit a femoral end component. . . . Preferably, the tool places drill holes in position for a standard set of cutting blocks to fit a femoral end component of a prosthetic knee.
- Column 1, Lines 50-54
 - Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur, while in flexion the joint gap is such as to place the femoral component in either neutral or external rotation to assure proper patellar tracking with the femoral component.
- Column 2, Lines 42-46
 - Accordingly, it would be desirable to provide a tool to simplify procedures during surgery for performing preparatory bone cuts or setting alignment marks to prepare the bone to receive a prosthetic joint component aligned with respect to the epicondylar axis.
- Column 2, Lines 56-61
 - The tool is used at the distal femoral resected surface, and includes one or more assemblies coupled to a main body for alignment with the epicondylar axis, and which set the orientation of the main body. The main body positions a cutter, e.g., includes a drill guide or saw blade guide.

- Figure 1

○

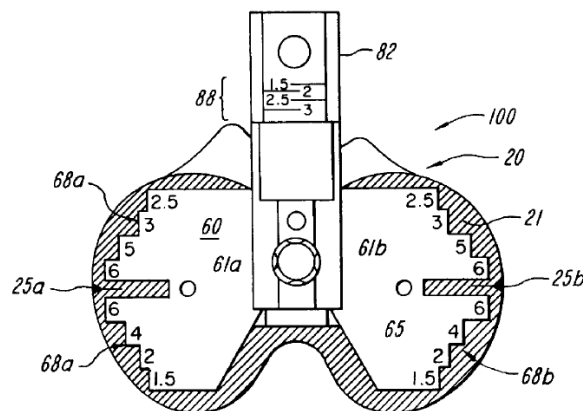


FIG. 1

- Column 3, Lines 46-61

- As shown in FIG. 1, a first prototype tool 100 is intended for use during surgery, and has a body which lies across the distal resected end 21 of a femur 20, which may be either the right or left femur. By way of overview, the tool is preferably used once the surgeon has made the distal femoral cut, and includes a central body 60 which includes a drill guide 61, and which is positioned across the distal bone end by an axis- or line-referencing assembly, discussed more fully below. In this embodiment the line-referencing assembly is implemented by a simple pair of viewing apertures or slots 65 in the body 60. As illustrated, the body 60 has been placed by the surgeon so that the apertures 65 are directly over a line or pair of marks 25a, 25b which are previously scribed by the surgeon to mark the projection of the epicondylar axis on the distal bone surface. So positioned, the body 60 places the drill guide holes 61 on the axis.

- Column 5, Lines 37-54

- It should be noted that the drill guide holes 61a, 61b illustrated in FIG. 1 correspond to a pair of positioning pins having a fixed spacing as used for example by one prosthesis manufacturer in all sizes of a line of femoral components. Those skilled in the art will recognize that this system employs a sequence of cutting blocks and other tools for preparing subsequent chamfers and faces of the bone termination which are also set, justified or otherwise positioned by the same two pin locating holes. However, the tool locator body 60 may be adapted in other embodiment as a saw cut guide rather than a drill guide, or both, in order to position a slot or other cut feature which similarly functions to orient and position one or more cutting blocks. Thus, for example, the tool positioning jig of the present invention may be configured for those prosthesis installation systems which rely upon first forming a slot parallel to or transverse to a given positioning axis, or first creating an anterior or posterior resection.

- Column 6, Lines 10-25

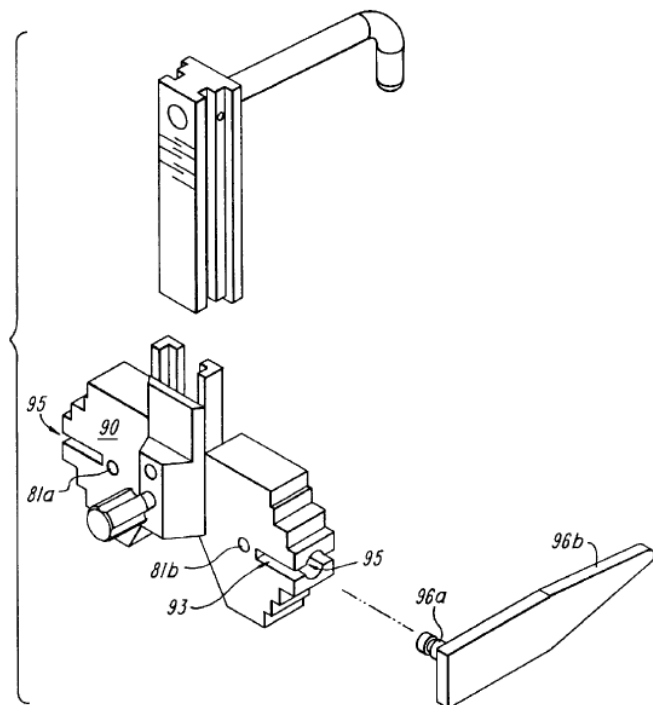
- As shown in FIG. 5A, the central body 90 of the component may be formed as a unit which, rather than being aligned by sighting slots 65 (FIG. 1), is provided with medial and lateral positioning bores 95, each of which accommodates a pointer arm 96 that may be moved in and out along the axis of the bore on a mounting shaft 96a so that the tip of the arm 96b is aligned with the prominence of the corresponding epicondyle. The two arms 96 thus position the body 90 parallel to the epicondylar axis. As further shown in FIG. 5B, a cross pin 97 extends through each shaft 96a to ride in a corresponding horizontal slot 93 that extends across the bore 95, so that the arm extends in a fixed direction across the plane of the body and does not rotate about the shaft 96a. This assures that when the arms are visually aligned with the epicondylar prominences or centers, the body 90 is oriented along the epicondylar axis.

- Column 6, Lines 46-50

- When the proper fit is achieved, holes are drilled into the distal resected femur using the drill positioning guide holes 81a, 81b. The device is then removed, and the surgical procedure continues using standard A/P cutting blocks pinned in the two drill holes so made.

- Figure 5A

○



A person of ordinary skill in the art would have been motivated to combine the teachings of Techiera with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Techiera teaches a tool with two guide holes used to set the rotation of an implant in relation to the epicondylar axis of the femur. *See, e.g.*, Techiera at 3:46-61, Fig. 1. Techiera also teaches that using a tool with drill holes to set the rotational alignment of an implant is desirable. *See, e.g.*, Techiera at 2:42-46 ("It would be desirable to provide a tool to simplify procedures during surgery for performing preparatory bone cuts or setting alignment marks to prepare the bone to receive a prosthetic joint component aligned with respect to the epicondylar axis."). Thus, a POSITA would be motivated to include drill holes in a tool for total knee arthroplasty that facilitate the

placement of a prosthesis according to a predetermined rotational alignment. Additionally, a POSITA would be motivated to apply the teachings of Techiera to any of Defendants' identified references as Techiera teaches rotational alignment of the femoral component can affect patellar tracking and thus the function of the knee replacement. *See, e.g.*, Techiera at 1:50-54. ("Generally, these cuts are formed so that in extension the joint gap is perpendicular to the mechanical axis of the femur, while in flexion the joint gap is such as to place the femoral component in either neutral or external rotation to assure proper patellar tracking with the femoral component."). Finally, Techiera and many of the references identified in Defendant's Invalidity Contentions come from the same field of invention—tools for knee arthroplasty. Thus, it would be obvious to a POSITA to combine one technique known in the art, *i.e.*, use of drill holes in a tool to set the rotational alignment of an implant, with any of the references identified in Defendant's Invalidity Contentions, with a reasonable expectation of success.

iii. Radermacher Thesis

- Page 96

- After a unique position has been identified, the template must be held or fixed in the reference position.

The "effect" to be taken into account for the position determination is then composed of the clamping or holding forces and the processing forces and torques. These in turn must be compensated by the normal forces at the contact points of the contact surface. Depending on the topography of the contact surface, as well as the amount and direction of the processing forces transmitted to the template, additional fixing can be avoided. Depending on the anatomical boundary conditions and access, additional fixation devices such as clamps, bone screws or cerclage wires can also be used for force-free fixation by a tight fit.

- Figure 4-28

○

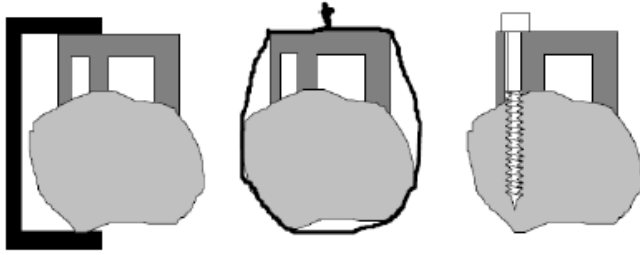


Figure 4-28: Schematic examples of (theoretically force-free) tight-fitting fixation using a clamp, cerclage wire or bone pin/screw

- Figure 4-36

○

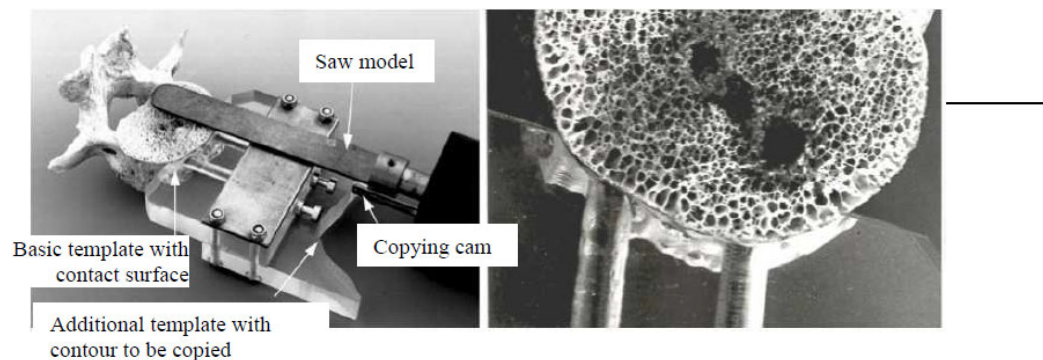


Figure 4-36: Ventral vertebral body osteotomy with depth-of-cut limitation: a) template and vertebral bone after osteotomy has been performed using the model of a TUKE saw with copying cam (the additional parallel guide was dismantled for display reasons). The contour to be copied and copying cam limit the movement of the tip of the saw blade exactly to the dorsal surface contour of the vertebral body; b) detailed image of the osteotomy plane showing the contact between CT-image-based base template and bone

- Figure 4-37

○

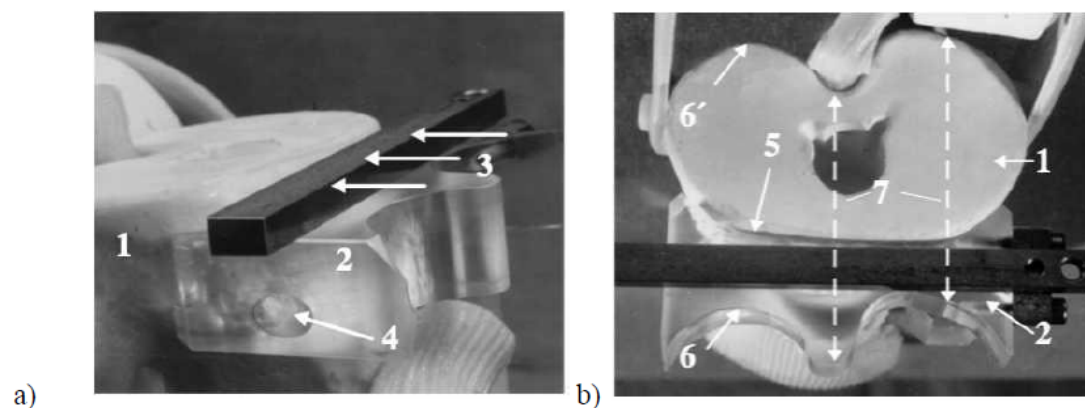


Figure 4-37: Individual template for guiding a tibial osteotomy for total knee arthroplasty – laboratory tests on a plastic model of a knee joint (1): a) The CT image-based customized template (2) precisely aligns the plane of the reference osteotomy (3). Optionally, the template can be fixed by bone pins (4). b) The CT image-based adapted contact surface (5) and contour to be copied (6) limit the depth of cut (7) to the dorsal surface contour (6') of the tibial bone.

- Figure 5-9

○

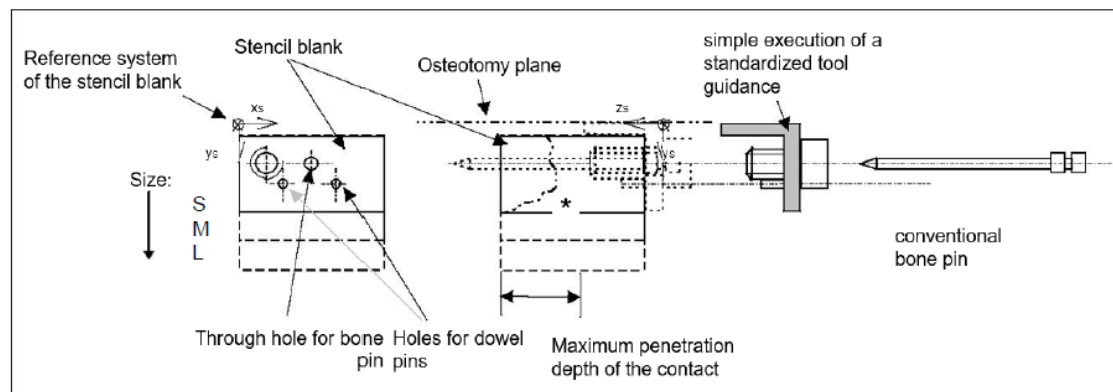


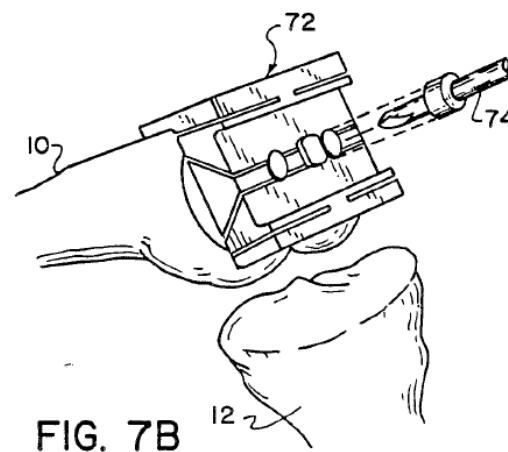
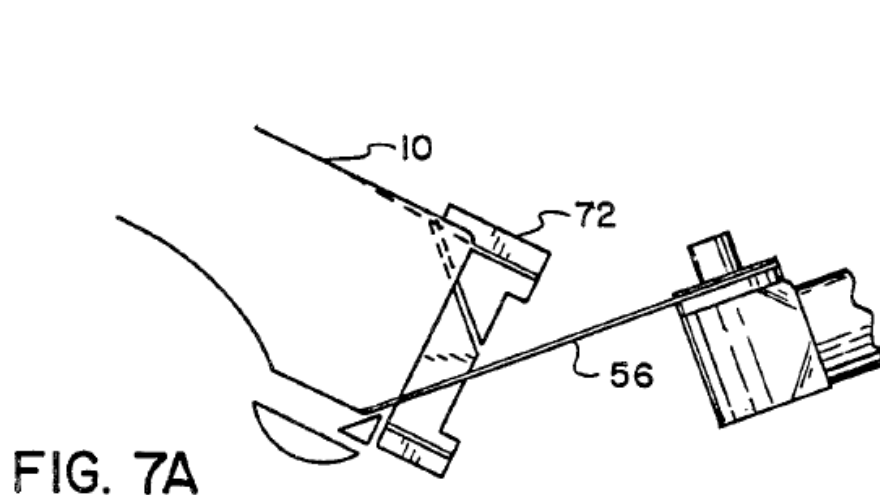
Figure 5-9: Simplified design of a standardized blank for individual osteotomy e-stencils (see Chapter 7, Figure 7-13). The tool guides can also be mounted or changed with the bone pin in place. The mounting position is clearly defined for all stencil sizes by dowel pins and is confusion-proof due to asymmetrical hole patterns.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher Thesis with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher Thesis teaches the concept of patient-specific templating and many of the charted references teach patient-specific templates for total knee arthroplasty. *See, e.g.,* Radermacher Thesis at 3 ("Chapter 4 presents the procedural system developed in the course of this work for computer-assisted coupling of preoperative planning, and intraoperative processing of bone structures with CT-based processing templates. First, the solution principle, as well as basics and aspects of the practical implementation of the method are explained. Based on individual bone geometry and planning data, mechanical tool guides are adapted before surgery using CAD/CAM components. The components and sequence of the entire procedure chain, from image acquisition and processing, operation planning and simulation to computer-aided design and manufacture of customized templates, will be designed. The requirements arising from different surgical applications require a differentiated design. Section 4.5 therefore presents drafts of customized templates for some exemplary applications from the field of orthopedic surgery and tests them on the bone model or anatomical specimen."). Furthermore, Radermacher Thesis teaches that when using patient specific templates, once "a unique position has been identified, the template must be held or fixed in the reference position," and one of the ways to fix the template is by inserting a bone pin through a guide

hole in a template. *See, e.g., id.* at 96; Fig. 4-28. Thus, to the extent not disclosed, a POSITA would be motivated to include one or more holes to accept a pin on a patient-specific template.

iv. Woolson

- Column 6, Lines 54-64
 - The final anterior, posterior and chamfer cuts on the femur are made after the proximal tibial cut has been made and a trial test of adequate bone resection has been made with the knee in extension using trial spacers, as is conventionally done. The final distal femoral cuts are made with a single conventional cutting guide 72 which is fixed in position on femur 10 by pins which are placed in holes drilled in the end of the femur which correspond to the pegs in the actual femoral prosthesis, as represented by the use of a drill 74. The resulting cuts by saw 56 are illustrated in FIG. 7A.
- Figures 7A & 7B
 -



A person of ordinary skill in the art would have been motivated to combine the teachings of Woolson with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that Woolson comes from the same field of invention as many of the references identified in the Defendants' Invalidity Contentions and teaches tools for total knee arthroplasty similar to many of the references identified in the Defendants' Invalidity Contentions. Furthermore, a POSITA would recognize that Woolson teaches using the same guides for pins and drilling holes for the prosthesis stem. Finally, Woolson teaches that proper alignment of a prosthesis relative to a mechanical axis is a factor in the long-term result of a total knee arthroplasty and discloses that its tools help achieve such alignment. *See, e.g.*, Woolson at 1:26-36 ("One of the most important causes for failure of the procedure is from prosthesis component loosening because of unbalanced loading of the tibial component caused by improper knee joint alignment. Because of this fact, all total knee implantation systems attempt to align the reconstructed knee joint in the mechanical axis in both the coronal and the sagittal planes. If achieved, this results in the placement of the total knee prostheses in a common mechanical axis which correspondingly is highly likely to produce a successful long-term result."). Thus, to the extent not already disclosed, a POSITA would be motivated to combine the teachings of Woolson with any of the references identified in Defendants' Invalidity Contentions and to include tool guides that can be used for pins, to drill holes for a prosthesis stem, or both.

L. "Articular Repair System" and "Implant" Limitations

Articular repair systems and implants, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
129	10	The instrument system of claim 1, wherein the instrument system is configured to position the orthopedic implant, wherein the orthopedic implant is a femoral component of a knee implant.
129	11	The instrument system of claim 1, wherein the instrument system is configured to position the orthopedic implant, wherein the orthopedic implant is a tibial component of a knee implant.
161	1	an articular repair system and
161	2	The surgical system of claim 1, wherein the articular repair system includes one or more implant components selected for the patient from preexisting systems.
161	19	an articular repair system and
482	1	an implant; and
482	17	an implant; and
780	3	moving the surgical instrument with the at least one guide to prepare the joint of the patient for receiving an implant.

This is illustrated, for example, in the following:

1. Applicant Admitted Prior Art

i. Asserted Patents

- '745 Patent, 36:53-56; '482 Patent, 36:62-65; '161 Patent, 36:64-67; '026 Patent, 29:13-16; '780 Patent, 29:27-30
 - These adjustments can be optimized for the implants of different manufacturers, e.g. Johnson&Johnson, Stryker, Smith&Nephew, Biomet and Zimmer.

- '745 Patent, 69:11-15; '482 Patent, 69:19-23; '161 Patent, 69:20-24; '129 Patent, 43-65-44:2; '304 Patent, 44:3-7; '026 Patent, 52:59-63; '780 Patent, 6-10
 - Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee.
- '745 Patent, 97:57-61; '482 Patent, 98:1-5; '161 Patent, 98:1-5; '026 Patent, 80:65-81:2; '780 Patent, 81:10-14
 - For example, a standard surgical cut block as described for standard implants, for example in the knee the J&J PFC Sigma system, the Zimmer Nexgen system or the Stryker Duracon system, can be connected or placed on the mold.
- ii. Ex Parte Re-Examination of '482 Patent, Declaration of Michael B. Mayor
- Paragraph 60
 - *Berez* describes patient-specific cutting guides for use in joint arthroplasty procedures. Ex.B at Title, Abstract; *see also id.* ¶¶ [0265]-[033 l]. The cutting guides have a surface that will match a portion of an articular or a bone surface. *Id.* ¶ [0266]. The guides also have apertures, slots, and/or holes to accommodate surgical tools such as saws and drills. *Id.* *Berez* explains that "[t]ypically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general [cutting guide] orientation for subsequent placement of an articular repair system [(implant)] or for facilitating placement of the articular repair system [(implant)]." *Id.* ¶ [0267].

2. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught that patient-specific and/or preexisting implants/articular repair systems could be implanted after the resection of a bone with a surgical tool. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, many of the Charted References taught that implants/articular repair systems can be implanted on the femur and/or tibia after a patient-specific tool is used to prepare the femur and/or tibia to receive the implant. Because many of the Charted References taught a patient-specific tool to prepare the femur and/or tibia for an implant, it would have been obvious to a POSITA that a pre-existing or patient-specific implant/articular repair system could be implanted on the bone after the tool performs the desired resections.

M. Cortical Bone Limitations

A surface being substantially a negative of cortical bone, including as recited in the following Asserted Claims, was well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions:

Patent	Claim	Claim Language
482	17	a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,

This is illustrated, for example, in the following:

1. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught a patient-specific surface that was substantially a negative of a cortical bone surface. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References taught that patient-specific surgical templates, which can have a surface that is substantially a negative of a cortical bone surface, including a cortical bone surface of the tibia and/or femur, can increase the accuracy of work done to the bone. Because many of the Charted References taught patient-specific surgical templates for use on the tibia or femur, a person of ordinary skill in the art would have found it obvious to include a surface that is substantially a negative of a cortical bone surface on a template disclosed in any of the references identified in Defendants' Invalidity Contentions.

2. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Radermacher CAOS

- Page 31

- In total knee arthroplasty accurate placement of implant components with respect to the individual mechanical axis of the leg is essential. Conventionally, modular mechanical devices corresponding to the intrinsic shape of the implant components are used to guide the osteotomies and bores for the preparation of the implant's seat. By mounting these conventional tool guide systems on an individual template as a basic customized reference, it is possible to reproduce the preoperatively planned position exactly even in the case of severely deformed bone.

- Figures 2A-B

-

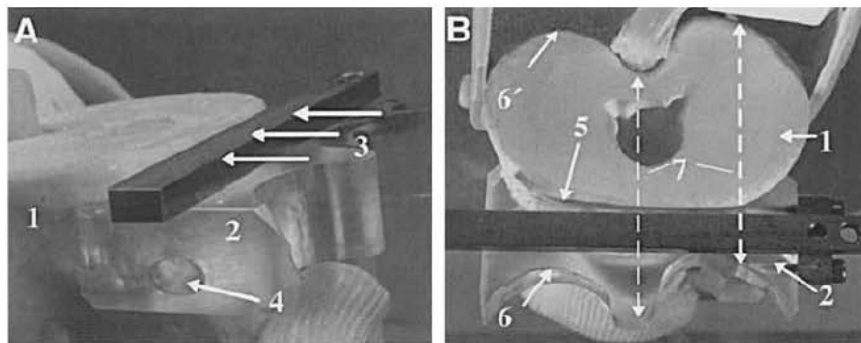


Fig 2A–B. Total knee arthroplasty: (A) laboratory investigation on a plastic bone model (1): individual template guiding the reference osteotomy (3) in tibial bone, optional fixation with a bone pin (4); (B) customized reference contact face (5) and copying profile (6) limiting cutting depth (7) to the dorsal contour (6) of tibial bone.

- Pages 31-32

- Figure 2 shows a feasibility study with a CT image based individual template for the reference tibial cut for total knee replacement on a plastic bone model.¹⁵ The geometry of the cut with its position, orientation, and limitations was planned on the basis of CT images (slices 2-mm thick and 2-mm apart). In addition, topograms could be used to identify the bone axis. A conventional saw guide can be mounted on the individual template, which serves as a reference base for subsequent work on the bone. The template has been customized in the areas of the reference surface and the individual copying profile

corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes.

A person of ordinary skill in the art would have been motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, Radermacher CAOS and many of the references identified in Defendant’s Invalidity Contentions, including the Charted References, come from the same field of invention and disclose patient-specific guides for total knee arthroplasty. Furthermore, a POSITA would recognize that the patient-specific template system taught in Radermacher CAOS, at least under the implicit claim construction from Conformis’ Preliminary Invalidity Contentions, can have a patient-specific surface that is a negative of cortical bone. Additionally, Radermacher CAOS teaches that these templates can increase accuracy. *See, e.g.*, Radermacher CAOS at 31-32 (“The template has been customized in the areas of the reference surface and the individual copying profile corresponding to the dorsal contour of the tibial bone within the cut plane. The accuracy of the reproduction was measured directly on the bone model using a conventional precision goniometer and a caliper gauge. The predefined cut plane and the position of the copying profile limiting the cutting depth were reproduced with an accuracy better than 1 mm in all directions and 1 ° inclination in the sagittal and transverse planes.”). Thus, a POSITA would be motivated to combine the teachings of Radermacher CAOS with any of the references identified in Defendants’ Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References.

N. Single Component Limitations

A patient-specific surface and guide being part of a single component, including as recited in the following Asserted Claims, were well known in the art prior to the time of the purported invention, at least under the claim constructions implicit in Plaintiff’s infringement contentions:

Patent	Claim	Claim Language
745	1	wherein the cutting block containing the patient-specific surface and the guide is a single component.

This is illustrated, for example, in the following:

1. Charted References

The prior art references charted in the Charted References further illustrate that the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. For example, the references charted in the Charted References taught wherein the cutting block containing the patient-specific surface and the guide is a single component. A person of ordinary skill in the art would have found it obvious to combine this well-known technique with any of the references identified in Defendants' Invalidity Contentions. For example, the Charted References come from the same field of invention—patient-specific templates for use in total knee arthroplasty, and many of the Charted References disclosed a template that is a single component. Thus it would be obvious to a person of ordinary skill in the art to modify a template for total knee arthroplasty disclosed in a charted reference such that it is a single component.

2. Additional References

The following prior art references provide further examples illustrating the claimed subject matter was well-known in the art prior to the purported invention, at least under the claim constructions implicit in Plaintiff's infringement contentions. *See, e.g.,*

i. Vomlehn

- [0035]
 - A design device 25, which may be a computer aided design (CAD) device, interacts with user 3 through user interface 17 to 'build' a reference structure 30, as shown in Fig. 2, having a mating surface 34, designed to fit flush against the surface of the solid structure at anchor site 6 of the subject. Design device 25 may be any conventional CAD device which allows input of other models.
- [0038]
 - In an optional embodiment, user 3 also may use a pointing device of user interface 17 to select a position and orientation (pose) which in a surgical instrument 40 is positioned in order to correctly insert the screw or pin. Design device 25 or graphics engine 21 may have a computer model of surgical instrument 40 pre-stored, and superimpose this model upon the images provided on monitor 23.

- [0040]
 - The final pose of surgical instrument may be used to construct a guide hole 31. Guide hole 31 allows is a shaft 41 of medical equipment, such as a surgical drill 40, to fit through snugly with little clearance, intended to restrain motion of the drill 40 along in all directions except along an axis of guide hole 31 .

- Figure 2

○

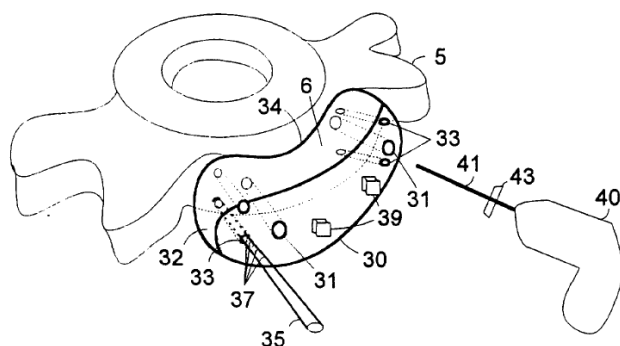


Fig. 2

A person of ordinary skill in the art would have been motivated to combine the teachings of Vomlehn with any of the references identified in Defendants' Invalidity Contentions, including but not limited to the particular combinations identified in the Charted References. For example, a person of ordinary skill in the art would recognize that the teachings in Vomlehn could be applied to a wide variety of orthopedic procedures, including total knee arthroplasty. *See, e.g.*, [0001] ("The present invention relates to computer-aided construction of a reference structure to be attached to a subject and act as a guide in medical procedures."); [0002] ("In various medical procedures, it is necessary to attach a piece of medical equipment into a solid structure of the subject."). Furthermore, Vomlehn teaches that its approach can increase the accuracy of medical procedures and eliminate estimation by surgeons or the use of intraoperative imaging. *See, e.g.*, [0006] ("Typically, these pins or screws have been inserted by a surgeon who visually, or by 'feel', finds the approximate location where the screw or pin should be entered, and drills a hole at that location. The screw or pin is inserted into the hole."); [0007] ("Sometimes, during surgery, two dimensional (2D) snapshots such as x-rays or magnetic resonance (MR) images may be obtained"); [0013]-[0014] ("Currently there is a

need for a device which may be attached to a subject and act as a reference structure to guide instruments during medical procedures. The present invention constructs a reference structure intended to be attached to a solid anchor site of a subject.”). Thus, to the extent not disclosed, a POSITA would be motivated to include a patient-specific surface and a guide on the same component.

Exhibit 5

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CONFORMIS, INC.,

Plaintiff,

v.

DEPUY SYNTHES, INC., DEPUY SYNTHES
PRODUCTS, INC., and DEPUY SYNTHES
SALES, INC.,

Defendants.

C. A. No. 21-640-RGA

**PLAINTIFF CONFORMIS INC.'S FIRST SET OF INTERROGATORIES
TO DEFENDANT DEPUY SYNTHES, INC. (NOS. 1-14)**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Plaintiff Conformis, Inc. requests that Defendant DePuy Synthes, Inc. respond to the following interrogatories within thirty (30) days after the date of service of these requests. The following definitions and instructions apply.

DEFINITIONS

1. “Defendant” or “Defendants” mean any and all defendants of the above captioned case, including DePuy Synthes, Inc., DePuy Synthes Products, Inc., DePuy Synthes Sales, Inc. and its officers, directors, current and former employees, counsel, agents, consultants, representatives and any other Persons acting on behalf of any of the foregoing, and any other legal entities, whether foreign or domestic, that are owned or controlled by it, and all predecessors and successors in interest to such entities.

2. “DePuy Synthes, Inc.,” “You,” or “Your” mean Defendant DePuy Synthes, Inc. and its officers, directors, current and former employees, counsel, agents, consultants, representatives and any other Persons acting on behalf of any of the foregoing, and any other

INTERROGATORY NO. 12:

For each asserted claim of the Asserted Patents which You contend You do not infringe, Describe Your complete legal and factual bases on a limitation-by-limitation basis, including by (1) identifying for each of the Accused Products each limitation of the asserted claims that You contend is not infringed; (2) identifying any alleged differences between each of the Accused Products that You contend are relevant and/or material to Conformis' infringement allegations; (3) explaining how each such alleged difference is relevant and/or material to infringement of each of the Asserted Patents; (4) Identifying all facts, witnesses, information, and documents that You allege support or are pertinent to Your contention of non-infringement; and (5) Identifying the Persons most knowledgeable about such contentions and bases.

INTERROGATORY NO. 13:

For each asserted claim of the Asserted Patents which You contend is invalid, under 35 U.S.C. §§ 101, 102, 103, 112, or otherwise, Describe Your complete legal and factual bases on a limitation-by-limitation basis, and identify all supporting documents. To the extent You allege anticipation or obviousness under §102 or § 103, identify each alleged prior art reference and the earliest priority date You contend that reference is entitled to. For obviousness contentions under § 103, include (a) where a combination of prior art is alleged to make a claim obvious, each specific combination of prior art for each claim and the motivation to combine such items at the time the invention was made; and (b) a detailed explanation as to why the prior art allegedly renders the element obvious, including any motivation to combine and secondary considerations.

INTERROGATORY NO. 14:

Identify any indemnification agreements relating to Your infringement of the Asserted Patents, and Describe the specific provisions and scope of any such indemnification agreements as they relate to Your infringement of the Asserted Patents.

DATED: March 29, 2022

/s/ Karen L. Pascale

An Attorney for Plaintiff, Conformis, Inc.

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on March 29, 2022, I caused a true and correct copy of the foregoing discovery document to be served upon the following counsel of record by electronic mail:

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/s/ Karen L. Pascale

March 29, 2022

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Attorneys for Plaintiff, Conformis, Inc.

Exhibit 6

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CONFORMIS, INC.,)	
)	
Plaintiff,)	C.A. No. 21-640-RGA
)	
v.)	
)	JURY TRIAL DEMANDED
DEPUY SYNTHES, INC., DEPUY)	
SYNTHES PRODUCTS, INC., and DEPUY)	HIGHLY CONFIDENTIAL –
SYNTHES SALES, INC.,)	ATTORNEYS’ EYES ONLY
)	
Defendants.)	

**DEFENDANTS’ OBJECTIONS AND RESPONSES TO PLAINTIFF
CONFORMIS, INC.’S FIRST SET OF INTERROGATORIES (NOS. 1–14)**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendants DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc. (collectively, “Defendants”) hereby provide the following objections and responses to the First Set of Interrogatories (Nos. 1–14) (“Interrogatories”), propounded by Plaintiff Conformis, Inc. (“Conformis”), as follows. Defendants have responded collectively for efficiency, and to ensure all responsive information and documents are provided. This expediency is not a concession that any information within the possession, custody, or control of any defendant is within the possession, custody, or control of the others. Each defendant is a separate legal entity, and some of the information below may be applicable to fewer than all Defendants.

PRELIMINARY STATEMENT

Defendants have not completed their investigation of all facts related to the subject matter of this action and Conformis has not yet identified the asserted claims, provided infringement contentions, or provided any other substantive discovery or disclosures. Defendants therefore make the following responses to the Interrogatories (the “Responses”) without prejudice to their right to produce, at any stage of these proceedings, different or additional facts or information.

INTERROGATORY NO. 12:

For each asserted claim of the Asserted Patents which You contend You do not infringe, Describe Your complete legal and factual bases on a limitation-by-limitation basis, including by (1) identifying for each of the Accused Products each limitation of the asserted claims that You contend is not infringed; (2) identifying any alleged differences between each of the Accused Products that You contend are relevant and/or material to Conformis' infringement allegations; (3) explaining how each such alleged difference is relevant and/or material to infringement of each of the Asserted Patents; (4) Identifying all facts, witnesses, information, and documents that You allege support or are pertinent to Your contention of non-infringement; and (5) Identifying the Persons most knowledgeable about such contentions and bases.

RESPONSE TO INTERROGATORY NO. 12:

Defendants incorporate herein by reference all General Objections set forth above.

Defendants further object to this Interrogatory as premature, as it calls for discovery into non-infringement positions before Conformis has disclosed its infringement contentions, or even its asserted claims, and expert discovery in advance of the dates contemplated by the parties' Scheduling Order and the Delaware Default Standard for Discovery or any ESI Order agreed upon by the parties, and before claim construction. Further, the Interrogatory has at least five subparts. With respect to sub-parts (2) and (3), the Interrogatory is vague and ambiguous, and to the extent it can be understood appears to seek information that is either privileged/work product, expert in nature, and/or disproportionate to the needs of the case at this juncture. Further, subpart (5) seeks information that is privileged/work product, expert in nature, and/or disproportionate to the needs of the case at this juncture.

Subject to and without waiver of the foregoing general and specific objections, Defendants will identify the elements as to which Conformis has not met its burden to show infringement at

an appropriate juncture in the case after infringement contentions and claim construction, including in expert reports.

INTERROGATORY NO. 13:

For each asserted claim of the Asserted Patents which You contend is invalid, under 35 U.S.C. §§ 101, 102, 103, 112, or otherwise, Describe Your complete legal and factual bases on a limitation-by-limitation basis, and identify all supporting documents. To the extent You allege anticipation or obviousness under §102 or § 103, identify each alleged prior art reference and the earliest priority date You contend that reference is entitled to. For obviousness contentions under § 103, include (a) where a combination of prior art is alleged to make a claim obvious, each specific combination of prior art for each claim and the motivation to combine such items at the time the invention was made; and (b) a detailed explanation as to why the prior art allegedly renders the element obvious, including any motivation to combine and secondary considerations.

RESPONSE TO INTERROGATORY NO. 13:

Defendants incorporate herein by reference all General Objections set forth above.

Defendants further object to this Interrogatory as premature because Conformis has not yet served infringement contentions, and Defendants' invalidity contentions are not yet due. Further, it is improper to seek "legal bases" through an Interrogatory. Additionally, Defendants object to the extent that the Interrogatory purports to seek different or additional information than is required under the Delaware Default Rules regarding invalidity contentions. Defendants further object that the Interrogatory improperly seeks to shift the burden to Defendants regarding secondary considerations. Conformis bears the burden and has not identified any purported secondary considerations.

Subject to and without waiver of the foregoing general and specific objections, Defendants will identify their invalidity contentions pursuant to the Scheduling Order.

INTERROGATORY NO. 14:

Identify any indemnification agreements relating to Your infringement of the Asserted Patents, and Describe the specific provisions and scope of any such indemnification agreements as they relate to Your infringement of the Asserted Patents.

RESPONSE TO INTERROGATORY NO. 14:

Defendants incorporate herein by reference all General Objections set forth above. Defendants further object that this interrogatory is irrelevant. Further, Defendants object that it is vague and ambiguous, and to the extent that it seeks legal conclusions.

Subject to and without waiver of the foregoing general and specific objections, pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, Defendants will produce any known indemnification agreements potentially applicable to this suit.

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*Attorneys for Defendants DePuy Synthes,
Inc., DePuy Synthes Products, Inc.,
and DePuy Synthes Sales, Inc.*

Dated: April 28, 2022

CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2022, true and correct copies of the foregoing document were caused to be served on the following counsel of record as indicated:

BY ELECTRONIC MAIL

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Exhibit 7

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CONFORMIS, INC.,

Plaintiff,

v.

DEPUY SYNTHES, INC., DEPUY SYNTHES
PRODUCTS, INC., DEPUY SYNTHES
SALES, INC.,

Defendants.

C.A. No. 21-00640-RGA

JURY TRIAL DEMANDED

**DEFENDANTS' SECOND SET OF INTERROGATORIES TO
PLAINTIFF CONFORMIS, INC. (Nos. 7-12)**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure, Defendants DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc. (“Defendants”) request that Plaintiff Conformis, Inc. (“Conformis”) respond in writing and under oath to the following Interrogatories within thirty (30) days after the date of service hereof. These Interrogatories impose a duty upon Conformis to promptly supplement in accordance with Federal Rule of Civil Procedure 26(e) as Conformis becomes aware of, generates, or acquires additional knowledge or information responsive to these Interrogatories.

DEFINITIONS

Each of these definitions is incorporated into each of the Interrogatories to which it pertains.

1. “You,” “your,” and “Conformis” mean Conformis, Inc., including all predecessors,

subsidiaries, parents, and affiliates, and all past or present directors, officers, agents, representatives, employees, consultants, attorneys, entities acting in joint-venture or partnership relationships with Conformis, and others acting on behalf of Conformis.

2. The term “Defendants” means DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc.

3. The term “Patents-in-Suit” means the seven patents identified in Conformis’s First Amended Complaint: U.S. Patent Nos. 8,460,304 (“the ’304 patent”), 9,295,482 (“the ’482 patent”), 8,623,026 (“the ’026 patent”), 9,326,780 (“the ’780 patent”), 9,186,161 (“the ’161 patent”), 8,377,129 (“the ’129 patent”), and 8,083,745 (“the ’745 patent”).

4. The term “person” refers to any natural person, firm, association, organization, partnership, sole proprietorship, business trust, corporation, or public entity.

5. The terms “document” or “documents” are used herein in their customary broad sense, and mean any kind of printed, recorded, written, graphic, or photographic matter (including tape recordings), however printed, produced, reproduced, coded or stored, of any kind or description, whether sent or received or not, including originals, copies, drafts, and both sides thereof, and including papers, books, charts, graphs, photographs, drawings, correspondence, telegrams, cables, telex messages, memoranda, notes, notations, work papers, routing slips, intra- and inter-office communications, electronic mail, affidavits, statements, opinions, court pleadings, reports, indices, studies, analyses, forecasts, evaluations, contracts, computer printouts, data processing input and output, computer programs, microfilms, microfiche, all other records kept by electronic, photographic, or mechanical means, and things similar to any of the foregoing, regardless of their author or origin, of any kind.

6. The terms “communication” and “communications” shall mean all written, oral,

telephonic or other inquiries, dialogues, discussions, conversations, interviews, correspondence, consultations, negotiations, agreements, understandings, meetings, letters, notes, advertisements, e-mail and all other documents evidencing any verbal or nonverbal interaction between persons.

7. The terms “and” and “or” are terms of inclusion and not of exclusion and are to be construed either disjunctively or conjunctively as necessary to bring within the scope of these requests any documents or responses which might otherwise be construed to be outside their scope.

8. Nouns, whether singular or plural herein, shall be construed either as singular or plural as necessary to bring within the scope of these requests any documents or responses which might otherwise be construed to be outside their scope.

9. The term “including” means “including without limitation,” as appropriate, so as to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope. The term “all” means “any and all,” as appropriate.

10. “Charted References” refers to the patents and publications charted in Defendant's invalidity contentions, and include:

- U.S. Patent No. 6,510,334 to Luis Schuster et al.;
- U.S. Patent No. 8,801,720 to Ilwhan Park et al.;
- U.S. Publication No. 2004/0236424 to Aaron Berez et al.;
- WO 1993/025157 to Klaus Radermacher et al.;
- WO 1995/028688 to Bart Swaelens et al.;
- M. A. Hafez, *Computer-Assisted Total Knee Arthroplasty Using Patient-Specific Templating*, 444 CLINICAL ORTHOPAEDICS & RELATED RSCH. 184 (2006);
- F. Portheine et al., *CT-Based Planning and DISOS Template Navigation in Knee Joint Arthroplasty*, in NAVIGATION AND ROBOTICS IN JOINT AND SPINE SURGERY (2002);

- F. Porthaine et al., *Modeling of Ligament Structures in CT Image-Based Planning of Knee Arthroplasty Procedures*, 47 BIOMEDICAL ENGINEERING 53 (2002); and
- F. Porthaine, *Model-Based Operation Planning in Orthopedic Surgery* (2004).

11. “OTDP Patents” refers to U.S. Patent Nos. 8,105,330, 9,295,482, and 8,657,827.

INSTRUCTIONS

1. In answering the following Interrogatories, you are instructed to furnish all available information, including information in the possession, custody or control of any of Conformis’s attorneys, directors, officers, agents, employees, representatives, associates, investigators, divisions, affiliates, partnerships, parents, subsidiaries and persons under Conformis’s control, who have the best knowledge, not merely information known to Conformis based on Conformis’s personal knowledge. Information is within your possession, custody, or control if, as a practical matter, you have the ability, upon request, to obtain the information.

2. If you cannot fully respond to the following Interrogatories after exercising due diligence to secure the information requested thereby, so state, and specify the portion of each Interrogatory that cannot be responded to fully and completely. State what efforts were made to obtain the requested information and the facts relied upon that support the contention that the Interrogatory cannot be answered fully and completely; and state what knowledge, information, or belief Conformis has concerning the unanswered portion of any such Interrogatory.

3. If you produce documents in connection with these Interrogatories, the documents produced should be organized and labeled to correspond to the categories in these Interrogatories.

4. If you withhold any information requested on grounds that it is protected from discovery by the attorney-client privilege, work-product doctrine, or other privilege, you must furnish a log providing the following information for each item of information withheld:

- a. the reason for withholding the information;
- b. the type of information and its subject matter;
- c. the date of the information;
- d. the name, organization, and position, if any, of each author, sender, and recipient of the information; and
- e. the name of the current or last known custodian of each document (if the information exists in document form).

5. If Conformis's response to a particular Interrogatory is a statement that it lacks the ability to comply with that Interrogatory, Conformis shall specify whether the inability to comply is because the particular item or category of information never existed, has been destroyed, has been lost, misplaced or stolen, or has never been or is no longer in Conformis's possession, custody, or control. Conformis shall identify the name and address of any person or entity known or believed by Conformis to have possession, custody or control of that information or category of information.

6. If part of any Interrogatory is objected to, please furnish information responsive to the remainder of the Interrogatory.

7. These Interrogatories are continuing. Pursuant to Rule 26(e) of the Federal Rules of Civil Procedure, additional documents or information that become known to you at any time hereafter must be furnished to Defendants within a reasonable time.

INTERROGATORIES

INTERROGATORY NO. 7:

If you contend that any Charted Reference does not disclose any element of any asserted claim for which it has been charted, identify that element and state the basis for your position.

INTERROGATORY NO. 8:

If you contend that the asserted claims of the '780 and '026 patents are patentably distinct from the claims of the OTDP Patents identified in Defendants' invalidity contentions, identify any elements of the asserted claims that you contend are not disclosed by, or obvious in view of, the claims of the OTDP Patents.

INTERROGATORY NO. 9:

If you contend that secondary considerations support non-obviousness for any asserted claim, describe them in detail and identify any supporting evidence, on a claim-by-claim basis.

INTERROGATORY NO. 10:

If you contend that any of Smith & Nephew's Visionnaire products, Stryker's ShapeMatch Cutting Guides, and Zimmer Biomet's Persona Patient-Specific Instruments did not practice the '745 and '129 patents at or before the time You filed the complaint in this action, identify by product the elements that allegedly are not present and the basis for your position.

INTERROGATORY NO. 11:

If you contend that any of Smith & Nephew's Visionnaire products, Stryker's ShapeMatch Cutting Guides, and Zimmer Biomet's Persona Patient-Specific Instruments did not practice the '780 and '026 patents at or before the time You filed the complaint in this action, identify by product the elements that allegedly are not present in that product and the basis for your position.

INTERROGATORY NO. 12:

If you contend that any products offered by you or an authorized licensee practiced any of the Patents-in-Suit at or before the time You filed the complaint in this action, identify the product(s), the practiced claims, and the basis for your contention.

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Dated: August 12, 2022

/s/ Kelly E. Farnan

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CERTIFICATE OF SERVICE

I hereby certify that on August 12, 2022, true and correct copies of the foregoing document were caused to be served on the following counsel of record by email:

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Exhibit 8

ORAL ORDER: The Court, having again reviewed the parties' briefing with regard to Plaintiffs' final lingering discovery dispute, (D.I. 307; D.I. 311; D.I. 317), addressed during the March 28, 2022 teleconference, and having reviewed Defendants' March 29, 2022 supplemental submission, (D.I. 329), hereby ORDERS as follows: (1) Plaintiffs' request that the Court compel Defendants to supplement Interrogatory No. 3 to confirm that they will not rely on any prior art other than the 41 identified references, absent a proper amendment, (D.I. 311 at 4), is DENIED. As Defendants note, (D.I. 317 at 4-5), this request appears to conflict with the Scheduling Order's May 26, 2022 deadline for final supplementation of all invalidity references, (D.I. 303 at 2).; and (2) With regard to Plaintiffs' remaining requests, (D.I. 311 at 4), they are GRANTED-IN-PART as follows. These requests are premised on Plaintiffs' assertion that Defendants' current response to Plaintiffs' Interrogatory No. 3 (which requests Defendants' contentions that the asserted claims of the patent-in-suit are invalid under 35 U.S.C. § 103), which in turn incorporates by reference Defendants' Joint Initial Invalidity Contentions (the "Initial Invalidity Contentions"), are unduly vague and insufficiently fulsome. (Id. at 3-4) The Court has reviewed the Initial Invalidity Contentions. In general, they provide real detail, including significant specificity as to: (a) the prior art references that could be a part of invalidity combinations, (see, e.g., Initial Invalidity Contentions at 54-114); (b) the portions of the prior art references that are relevant to Defendants' obviousness arguments, (see, e.g., id. at Appendix A); and (c) why a person of ordinary skill in the art might be motivated to combine the teachings of certain prior art references, (see id. at 128-31, 136-47). That said, the one area as to which the Court has sympathy for Plaintiffs' position is that in the Initial Invalidity Contentions, Defendants generally state that the asserted claims are obvious over many possible combinations of many different references, (see, e.g., id. at 132), which makes it difficult for Plaintiffs to know exactly which specific combinations are being asserted against them. On that score, Plaintiffs should get some relief. In terms of how and when that relief should be provided, the Court repeatedly suggested that if Plaintiffs were willing to narrow the number of asserted claims, then the Court could require Defendants to then cut down to a specific number of invalidity combinations by a date certain. But Plaintiffs did not seem particularly interested in that option during the teleconference. In light of this, and in light of the fact that the deadline for final invalidity contentions is coming up soon, the Court hereby ORDERS that by June 22, 2022, the date when Defendants' final invalidity contentions are due, Defendants shall: (a) identify in those final invalidity contentions the specific invalidity combinations they intend to rely upon (without the use of terms like "exemplary" and "and/or"); (b) provide fulsome detail regarding the obviousness arguments for those specific invalidity combinations; and (c) supplement their response to Interrogatory No. 3 by incorporating the final invalidity contentions into that response. Ordered by Judge Christopher J. Burke on 4/21/2022. (mlc) (Entered: 04/21/2022)

As of April 22, 2022, PACER did not contain a publicly available document associated with this docket entry. The text of the docket entry is shown above.